Perinatal HIV Prevention Grantee Meeting Summary

Plenary Sessions and Workshops

February 27-28, 2001
Atlanta, Georgia

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Opening Remarks - I

David Holtgrave
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In recent years, mother-to-child HIV transmission has been drastically reduced in the United States – from a high of 2,500 in 1992 to less than 400 perinatal HIV infections annually. This reduction is due to the widespread adoption of routine HIV counseling and voluntary testing for pregnant women and the availability of zidovudine (ZDV or, more commonly, AZT) and other drugs to interrupt transmission from the pregnant woman to her baby.

But even with these successes, CDC estimates that, overall, approximately 40,000 people per year in the United States become infected with HIV, a number that has remained relatively stable–*but unacceptably high*–for much of the past decade.

CDC has developed a new strategic plan for HIV prevention to further our national efforts to effectively address HIV infection and AIDS at home and abroad. I would like to take a few brief minutes to discuss how the important work that you are doing fits into the overall goal of this strategic plan.

The overarching goal of the plan is to reduce the number of new HIV infections in the United States from an estimated 40,000 to 20,000 per year by 2005, focusing particularly on eliminating racial and ethnic disparities in new HIV infections. To reach this overarching goal, the plan includes an objective related to the prevention of perinatal HIV transmission: Increase the proportion of HIV-infected pregnant women who routinely receive HIV counseling, accept HIV testing and choose to take antiretroviral medication to interrupt perinatal transmission of HIV.

Strategies to accomplish this objective include:

1. Routinize voluntary HIV counseling and testing, with informed consent, for all pregnant women, including those with no prenatal care.
2. Increase HIV-infected women's and HIV-exposed infants' early access to appropriate prevention (including elective cesarean section) and treatment.
3. Through capacity building and technical assistance, increase the proportion of prevention providers funded by CDC who successfully provide demonstrably effective, culturally competent mother-to-child HIV prevention interventions.
4. Increase early and comprehensive prenatal care for all pregnant women, regardless of income, insurance or ability to pay.
5. Research, develop, implement and evaluate interventions to address barriers to the use of antiretroviral medications for perinatal HIV prevention by women at high risk.
6. Assess the acceptability, implementation and effects on testing rates of rapid HIV antibody screening among women in labor who had no prenatal care or who were not tested despite having had prenatal care.
7. Assess the effectiveness of ultrashort antiretroviral regimens for pregnant women and their

infants when care is not obtained until labor and delivery.
8. Research, develop, implement and evaluate evidence-based mother-to-child transmission prevention programs for HIV-infected pregnant women who use injection drugs, alcohol and other drugs (e.g., crack cocaine, crystal methamphetamine).
9. Research, develop, implement and evaluate interventions to address structural-level barriers to effective mother-to-child transmission prevention.

You are already involved in many of these strategies in the work that you do. And over the next two days, you will share with each other and with CDC what your experiences have been over the last year as you have implemented, and in some cases enhanced, the work that you have done related to these strategies. However, even though we have reason to believe that we are relatively close to eliminating the perinatal transmission of HIV, there is still much work to do and that is why this meeting is so critical.

Thank you for the extremely important work that you do! We look forward to the next two days and sincerely appreciate your role in assisting our nation's HIV prevention efforts.

Opening Remarks - II

Rob Janssen
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The perinatal HIV prevention initiative is based on congressional funding first appropriated in the fall of 1999. To maximize the impact of the initiative, funding was awarded to states with high HIV seroprevalence among childbearing women and to states with high numbers of perinatal AIDS cases.

Cornerstones of the initiative include development of strategies to improve outreach to high-risk women, to increase antenatal voluntary counseling and testing, and to increase participation in perinatal HIV interventions. The initiative challenges us to use these funds to improve links among HIV prevention, antenatal, drug abuse, and Maternal Child Health services and, in so doing, to provide optimal care for HIV-infected women and their infants.

There has been dramatic progress in reducing perinatal HIV transmission in the U.S. over the past 7 years. However gaps still remain, particularly for those women not accessing antenatal care services.

There are a number of crucial partners working with CDC and the states in these perinatal HIV prevention efforts. These include our PHS partners at NIH including NICHD, NIAID, NIDA, as well as our partners at SAMSHA and HRSA. In addition, the ongoing work by NASTAD in supporting HIV prevention and care has been crucial to the successes so far, as has that of national health care organizations in developing educational materials and training.

Medicaid funding has and will continue to be important at the state level in financing the health care

costs of perinatal HIV prevention, care and treatment for HIV-infected women, children and youth. The role of national health care provider organizations in training health care providers on prevention of perinatal HIV prevention has also been critical to the successes and progress to date.

The next several days will provide a forum and opportunity to hear about the varied and exciting programs that have been developed by the states and national health care provider organizations to help reduce perinatal HIV transmission to the lowest levels possible in the U.S., and to share lessons learned and materials. Thank you for all your hard work over the past year. We look forward to learning about your progress during this meeting and about how we can further assist you.

Legislative History of RWCA Perinatal Program

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National Alliance of State and Territorial AIDS Directors

The National Alliance of State and Territorial AIDS Directors (NASTAD) represents the nation's chief state health agency program directors who have responsibility for administering HIV/AIDS health care, prevention, education, and supportive service programs funded by state and federal governments. NASTAD is funded by CDC to provide peer-based technical assistance to health departments and community planning groups on HIV prevention planning and programs.

Section 2625 of the Ryan White CARE Act (RWCA) Amendments of 1996 authorized grants to states for activities to reduce perinatal transmission of HIV including:

- "Making available to pregnant women appropriate counseling on HIV disease."
- "Making available outreach efforts to pregnant women at high risk of HIV who are not currently receiving prenatal care."
- "Making available to such women voluntary HIV testing for such disease."
- "Offsetting other State costs associated with the implementation of this section and subsections (a) and (b) of section 2626."
- "Offsetting State costs associated with the implementation of mandatory newborn testing in accordance with this title or at an earlier date than is required by this title."

Funding in the amount of $10 million was authorized. Funding priorities were indicated: "In awarding grants under this subsection the Secretary shall give priority to States that have the greatest proportion of HIV seroprevalence among childbearing women using the most recent data available as determined by the CDC."

In FY 1999, Congress appropriated $10 million for CDC to implement Section 2625 of the Ryan White CARE Act Amendments of 1996. The report language accompanying the FY 99 funding bill placed emphasis on state-administered activities including outreach, counseling, and voluntary testing of

pregnant women. It did not emphasize mandatory testing of newborns.

The Ryan White CARE Act Amendments of 2000 authorize $30 million for grants supporting counseling, testing, and treatment of pregnant women and infants. The first $10 million is for existing programs under current law.

For funds authorized above $10 million, a percentage is reserved for states that require newborn testing and for a select number of states that have had significant reductions in cases of perinatal transmission. Grants to these states cannot exceed $4 million. The percentage of money reserved for these states increases over time: FY 2001 - 33 %; FY 2002 - 50%; FY 2003 - 67%; FY 2004 - 75%; FY 2005 - 75%. The number of states with reduction in cases to be included in the reserved pot also increases over time: FY 2001 - 2 states; FY 2002 - 2 states; FY 2003 - 3 states; FY 2004 - 3 states; FY 2005 - 4 states.

In FY 2001 only, a special funding rule stipulates that $4 million of the appropriated increases in Title II shall be used for grants to states to reduce perinatal transmission. Of this $4 million, 50% is for the restricted pot.

The RWCA Amendments of 2000 also called for a new Institute of Medicine (IOM) study:

- to determine the number of newborns with HIV, in which the attending obstetrician did not know the HIV status of the mother;
- to determine barriers for states that prevent or discourage an obstetrician from routinely testing pregnant women for HIV and routinely testing newborn when the mother's status is unknown; and
- to recommend to states ways to remove barriers and reduce incidence of transmission.

In FY 2004, states will have to submit a report to the Secretary of DHHS on actions taken to address recommendations in the IOM report. The Secretary will submit a report to Congress that includes the states' "progress" reports.

In conclusion, the "take-home" messages for CDC are: a) to get the money out the door as soon as possible and streamline as much as possible the process of determining and making awards; and b) to remember the unique state and local health department role in planning, coordinating, and implementing perinatal prevention activities within the continuum of prevention and care programs.

The "take-home" messages for grantees and CDC are that: a) the $4 million in FY 2001 may be one-time funding under the special rule; b) there is a great deal of interest in the implementation of these provisions and likely to be a high level of public scrutiny; and c) there is a need to examine cost-effectiveness for these resources as compared to other primary prevention activities.

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Update on Public Health Service Task Force Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the U.S.

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Data from the Women and Infants Transmission Study for the period 1990-1999 clearly indicate a decreasing rate of mother-to-infant transmission as an increasing percentage of pregnant women received ZDV monotherapy and, increasingly in more recent years, multi-regimen antiretroviral therapy (multi-ART) or highly active antiretroviral therapy (HAART). In 1990 with less than 5% of HIV-infected pregnant women in the study on ZDV monotherapy (prior to the introduction of the prophylactic regimen documented by PACTG 076), the transmission rate was 22.7 per 100 live births. In 1999, with more than 95% of pregnant women in the study on some form of antiretroviral therapy, the rate was 3.3 per 100 live births.

Public Health Service guidelines for reducing vertical transmission of HIV were first published in 1994, within 6 months of the presentation of PACTG 076 results. The latest *printed* guidelines appeared in a January 30, 1998 *MMWR Recommendations and Reports*. Since 1999, a perinatal HIV guidelines working group, consisting of outside consultants as well as PHS representatives, have reviewed the latest data and developed updates to the guidelines through a monthly conference call. Updates are posted continuously on the HIV/AIDS Treatment Information Service website (www.hivatis.org), sponsored by several HHS agencies.

Today I will present the major updates to the guidelines since their publication in the 1998 *MMWR*. Briefly stated, they include:

- addition of a section on preconception counseling
- update on mitochondrial toxicity issues in pregnancy and in utero antiretroviral exposure
- recommends HAART if HIV RNA >1,000 (can discontinue postpartum)
- addition of NVP if RNA+ at delivery is **not** recommended
- resistance testing same as for non-pregnant women
- recommendations for intrapartum/postpartum regimens
- ARV administered >48 hours postpartum only to newborn is unlikely to be effective
- elective cesarean section for reducing transmission.

Preconceptional Counseling and Care for HIV-Infected Women of Childbearing Age: What Should Be Discussed *Before* Pregnancy

Before pregnancy, the following counseling and care should be provided to HIV-infected women of childbearing age:

- contraception to reduce unintended pregnancy (well over 50% of pregnancies in the U.S. are

unintended)
- counseling re: perinatal transmission and prevention
- initiate/modify ARV therapy before conception
    - avoid drugs with possible reproductive toxicity
    - choose drugs effective in reducing perinatal transmission
    - attain stable, maximally suppressed viral load
    - evaluate/treat ARV side effects that could effect maternal-fetal outcome (hyperglycemia, hepatic toxicity, anemia)
- evaluate OIs, need for prophylaxis, immunizations
- optimize nutritional status
- standard (history, STD screen, folate/vitamins)
- screening for substance abuse.

Principles Related to Antiretroviral Drug Use by HIV-Positive Pregnant Women and Their Infants

Therapies of known or potential benefit should not be withheld during pregnancy unless:

- there are known adverse effects on the mother, fetus or infant; and
- these side effects outweigh potential benefit to the woman.

Special considerations regarding drug choice would be: a) antiretroviral pharmacokinetics in pregnancy, and b) potential toxicities to pregnant woman and/or her fetus.

A decision regarding use of antiretrovirals during pregnancy should be made by the woman following discussion of known and unknown benefits and risks. The discussion should include information on:

- AZT efficacy for reducing transmission
- antiretrovirals recommended for her own health
- relationship between transmission and HIV RNA
- potential efficacy of elective cesarean delivery in reducing transmission
- unknown long-term risks of in utero exposure.

A long-term treatment plan should be developed for the woman and follow-up planned for the infant. Providers should also discuss general preventable risk factors for transmission (drug use, smoking, multiple sexual partners).

It is strongly recommended that health care providers who are treating HV-1 infected pregnant women and their newborns report cases of prenatal exposure to antiretroviral agents (either alone or in combination) to the Antiretroviral Pregnancy Registry, whose purpose is assess the potential teratogenicity of these drugs (phone 800-258-4263 or fax 800-800-1052).

General Considerations in Therapeutic Decision-Making for HIV-Positive Pregnant Women

General considerations in therapeutic decision-making for HIV-positive pregnant women include:

- gestational age of pregnancy
- HIV RNA level
- CD4 cell count
- clinical stage
- antiretroviral treatment history
- prevention of perinatal transmission
- safety/toxicity for mother and infant.

Special Considerations on Antiretroviral Drug Use by HIV-Positive Pregnant Women and Their Infants

Special considerations on antiretroviral drug use by HIV-positive pregnant women and their infants should include:

- drugs with higher teratogenic risk (efavirenz, hydroxyurea)
- combination antiretroviral therapy and preterm delivery (conflicting data)
- protease inhibitors and hyperglycemia
- mitochondrial toxicity and nucleoside analogues:
  - pregnancy – lactic acidosis, hepatic steatosis, pancreatitis (d4T/ddI fatalities)
  - fetus/infant – theoretical mitochondrial toxicity with in-utero exposure
    - Blanche S, et al. "Possible mitochondrial dysfunction and perinatal exposure to nucleoside analogues." *Lancet* 1999;354:1084-9.
    - Perinatal Safety Review Working Group. "Lack of death due to mitochondrial disease in children who died at <5 years in 5 U.S. cohorts." *JAIDS* 2000;25:261-8.

Following are various scenarios related to antiretroviral prophylaxis

Antiretroviral Prophylaxis Scenario 1: HIV-positive pregnant women who have not received prior antiretroviral therapy

- Conduct standard clinical, CD4 and RNA evaluations.
  - Blattner W. "Delivery plasma HIV RNA levels and perinatal transmission in WITS, 1990-1999." *XIII AIDS Conf*, July 2000, Durban S Africa (LBOr4)
  - Ioannidis JPA, et al. "7-Cohort meta-analysis of transmission from mothers with delivery HIV RNA <1,000." *J Infect Dis* 2001;183(4):539-45.
- 3-part 076 AZT regimen recommended to reduce perinatal transmission.
- Combine AZT prophylaxis with additional drugs to treat HIV infection:
  - Recommend for women whose clinical, CD4 or RNA status requires treatment.
  - Strongly consider for any woman with RNA >1,000.
- Women in 1st trimester may consider delaying therapy until after 10-12 weeks gestation.

Antiretroviral Prophylaxis Scenario 2: HIV-positive pregnant women receiving antiretroviral therapy during the current pregnancy

- If pregnancy identified after 1st trimester, continue therapy.
- If pregnancy identified during 1st trimester, discuss risks/benefits; if discontinue, all drugs should be stopped and restarted at same time.
- AZT should be a component of regimen after 1st trimester whenever possible.
- AZT is recommended intrapartum and to newborn regardless of maternal antenatal regimen.
- Resistance testing recommendations same as for non-pregnant (acute infection, virologic failure).
- The addition of intrapartum/newborn nevirapine is not recommended for women already receiving antenatal antiretroviral treatment who still have detectable viral load, as data from a clinical trial does not indicate this offers additional benefit in reducing transmission and has a risk of inducing nevirapine resistance.
  - Dorenbaum A. "Transmission in PACTG 316 by treatment arm.". *8th Retrovirus Conf*, Feb 2001, Chicago, IL (Abstract LB7)
  - Sullivan J. "PACTG 316: NVP resistance in women receiving ARV treatment with delivery HIV RNA >3,000." *XIII AIDS Conf*, July 2000, Durban, S. Africa (LbOr014).

Antiretroviral Prophylaxis Scenario 3: HIV-positive pregnant women in labor who have had no prior antiretroviral therapy

- Several intra-/postpartum regimens are available:
  - 2-dose nevirapine
  - AZT/3TC
  - AZT
  - 2-dose nevirapine plus AZT
- In immediate postpartum period, standard assessments (CD4, RNA) should be performed to determine whether antiretroviral therapy should be recommended for treatment of HIV disease.

Scenario 3:
Intrapartum/Postpartum Prophylaxis Regimens

Drug	Source of Evidence	Regimen	Efficacy
Nevirapine	HIVNET 012, SAINT	IP: 1 dose onset labor PP: 1 dose infant 48 hrs	47% reduction (vs ultrashort AZT)
AZT/3TC	PETRA, SAINT	IP: Oral PP: Infant 1 wk	38% reduction
AZT	Observational (Wade, Fiscus)	IP: Intravenous PP: Infant 6 wks	62% reduction
AZT/ Nevirapine	Theoretical	Combine Nevirapine and AZT regimen	?

Antiretroviral Prophylaxis Scenario 4:Infants born to HIV-positive women with no therapy during pregnancy or intrapartum

- 6-week neonatal AZT prophylaxis recommended.
- AZT should be initiated within 6-12 hours of birth; after 48 hours it is unlikely to be effective.
  - Wade NA, et al., "Abbreviated regimens of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus." *N Engl J Med* 1998; 339:1409-14.
- Some clinicians may choose to give AZT combined with other antiretrovirals, but efficacy unknown and appropriate dosage and safety incompletely defined.
- In immediate postpartum period, standard assays (CD4, RNA) should be performed to see whether antiretroviral therapy recommended for mother.
- Infant should have early diagnostic testing to allow early treatment if found to be infected.

Elective Cesarean Section to Prevent Perinatal Transmission

A recent European study suggested that delivery by elective cesarean section (C/S) may reduce vertical transmission of HIV (European Mode of Delivery Collaboration. "European randomized mode of delivery trial: elective cesarean at 38 weeks vs. vaginal delivery." *Lancet* 1999;353:1035-9). Similarly, a meta-analysis of 15 cohort studies showed elective C/S reduced the risk of transmission by 50% in women not receiving antiretrovirals and by 70% in women receiving AZT prophylaxis (International Perinatal HIV Group. "The mode of delivery and the risk of vertical transmission of human immunodeficiency virus type 1--a meta-analysis of 15 prospective cohort studies." *New England Journal of Medicine* 1999 Apr 1;340(13):977-87). Elective C/S is defined as C/S occurring PRIOR TO labor and/or rupture of membranes. Four possible mode-of-delivery scenarios are presented here:

Mode-of-Delivery Scenario A: HIV-positive woman >36 wks gestation, no ARV therapy, HIV RNA/CD4 pending but unlikely available before delivery

- Start antiretroviral therapy, including at least AZT.
- Discuss therapy options.
- Counsel elective C/S likely to reduce transmission.
- Inform C/S risks (surgical, anesthesia, post-op infection).
- Schedule C/S at 38 weeks gestation.
- Intrapartum IV (start 3 hours before C/S) and infant 6 week AZT should be given.
- Discuss options to continue or start combination antiretrovirals postpartum once RNA/CD4 return.

Mode-of-Delivery Scenario B: HIV-positive woman starting HAART 3rd trimester with initial viral response but HIV RNA substantially >1,000 copies/ml at 36 weeks gestation

- Continue HAART, as RNA level dropping appropriately.
- Counsel that unlikely RNA will be <1,000 by delivery.
- Therefore, elective C/S may provide additional benefit in reducing intrapartum transmission to infant.
- Inform C/S risks.
- Intrapartum and infant 6-week AZT should be given.

- Continue other antiretrovirals on schedule as much as possible before/after surgery.
- Emphasize importance of HAART adherence.

Mode-of-Delivery Scenario C: HIV-positive woman on HAART with HIV RNA level undetectable at 36 weeks gestation

- Continue HAART.
- Counsel that risk transmission when on ARV and with persistent undetectable RNA is low (<2%), even with vaginal delivery.
- There is currently no information to evaluate whether elective C/S will substantially lower risk further.
- C/S has increased risk of complications for woman compared to vaginal delivery, which should be balanced against uncertain benefit of C/S in this case.
- Intrapartum and infant 6-week AZT should be given.

Mode-of-Delivery Scenario D: HIV-positive woman with planned elective C/S but who present early in labor or shortly after membrane rupture

- Start IV AZT immediately since woman in labor and/or ruptured membranes
- If labor progressing rapidly, allow vaginal delivery.
- If cervical dilatation minimal and long labor anticipated, some clinicians may choose to give AZT IV loading dose and proceed with C/S to minimize duration membrane rupture and avoid vaginal delivery.
- Others might begin pitocin augmentation to enhance contractions and potentially expedite delivery; avoid invasive procedures (e.g., scalp electrodes).
- Infant should receive 6 weeks of AZT.

Virologic, Immunologic and Other Monitoring During Pregnancy

During the pregnancy of HIV-infected women, providers should monitor:

- CD4 count: same as non-pregnant.
  - baseline (diagnosis pregnancy), q 3-4 months
- HIV RNA: same as non-pregnant.
  - baseline (diagnosis pregnancy), prior to therapy, 4 weeks after start/change therapy, q 3-4 months.
- resistance testing: same as non-pregnant
  - acute infection or virologic failure
- additional monitoring based on antiretroviral drug:
  - NRTI – lactic acidosis, hepatic steatosis
  - NNRTI – rash, hepatitis
  - PI – hyperglycemia, preterm delivery (?)

Monitoring of the Newborn
Monitoring of the newborn should include:

- CBC: minimum monitoring for hemoglobin/ neutrophil count:
  ---- at birth/baseline
  ---- 6 weeks
  ---- 12 weeks
  ---- more frequent if anemic at birth or premature
- If other antiretrovirals are given, more frequent or intensive (e.g., liver function tests) monitoring may be warranted.
- PCP prophylaxis:
  ---- initiate at age 4-6 weeks
- HIV virologic diagnostic testing:
  ---- birth – 48 hours
  ---- 2 weeks
  ---- 1-2 months (after chemoprophylaxis finished)
  ---- 3-6 months.

Progress Towards Elimination of Perinatal HIV Infection in the United States

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Today I will present population-based HIV/AIDS surveillance data highlighting and updating the remarkable changes in the epidemiology of perinatal HIV infection and recent efforts to significantly reduce perinatal HIV transmission. These data suggest it may be possible to consider the goal of elimination of perinatal HIV infection in the U.S. But, challenges still remain.

The public health definition of elimination is the reduction to zero of the incidence of infection caused by a specific agent in a defined geographic area as the result of deliberate efforts; continued measures to prevent reestablishment of transmission are required.

An elimination program requires a highly efficacious intervention. In 1994, maternal and neonatal zidovudine use in PACTG 076 reduced mother-to-child transmission by 67%. Since then, clinical trials in international settings have shown that abbreviated antiretroviral regimens, such as short course zidovudine and intrapartum regimens such as Nevirapine, are also effective in reducing perinatal transmission. Combination antiretroviral therapy for the mother's health that reduces viral load to undetectable levels may lower the risk of transmission to < 1% and elective cesarean section combined with ZDV reduced rates to 1-2%. Thus, multiple effective strategies are now available to reduce mother-to-child HIV transmission.

Surveillance is a critical part of an elimination program and must be used to guide program strategy. The efforts in each of the states to use the enhanced HIV surveillance data for targeting and evaluating local programmatic efforts are essential. Enhanced surveillance efforts are needed with successive stages of elimination. Highly effective implementation efforts are also essential.

The U.S. Public Health Service issued recommendations in 1994 for ZDV use and in 1995 for universal prenatal HIV counseling and voluntary testing. In 1998, the Institute of Medicine reported widespread implementation of these recommendations, but barriers, such as the lack of routine, voluntary prenatal HIV testing and of prenatal care, remain. To address these barriers and further reduce perinatal transmission, CDC funded both programmatic and surveillance efforts in states with the highest burden of disease.

Progress Towards Elimination

Three sources of state-level data allow us to assess progress towards elimination. Enhanced perinatal HIV surveillance was previously conducted in seven states with HIV reporting. In addition to active HIV case surveillance, these states matched HIV/AIDS and birth registries for infant birth years 1993 and 1995-1997 to identify additional mother-infant pairs. Maternal HIV clinic, prenatal, labor and delivery, and newborn and pediatric records were reviewed to provide more complete and accurate data. Now, enhanced perinatal surveillance has been expanded to 22 states.

Data were also evaluated from 33 states that conduct routine, active HIV case surveillance and monitor prenatally- exposed children for their HIV status. Data are collected on demographics, prenatal care, illicit drug use during pregnancy, maternal HIV testing, antiretroviral use, birth history, and HIV status.

Finally, we evaluated national AIDS surveillance data on prenatally-acquired AIDS cases reported through December 2000 to look at trends in diagnoses through June 2000, adjusting for reporting delay and risk redistribution. To estimate perinatal HIV incidence in the U.S., the birth distribution of prenatally- acquired AIDS was adjusted for time to AIDS and reporting delay.

Of course the most important perinatal prevention strategy is to prevent HIV infection in women. Through June 2000, 753,907 cases of AIDS have been reported, and 438,795 deaths. In association with the widespread use of highly active antiretroviral therapy, a marked decline in AIDS incidence and deaths began in 1996 and continued into 1998. However, rates of decline in AIDS incidence and deaths slowed during the latter part of 1998 and 1999, probably for several reasons (limits of treatment in extending survival, failing therapies due to resistance, late HIV testing, inadequate adherence or access to therapies, and a recent increase in incidence in some risk groups). AIDS prevalence continues to rise, with approximately 320,000 persons living with AIDS at the end of 1999.

Women account for 17% of all AIDS cases and 20% of all prevalent cases. Over 64,000 women were living with AIDS in 1999. Most women with AIDS are members of racial or ethnic minorities. During the 1990's, women, minorities and persons infected through heterosexual contact represented a growing proportion of annual AIDS cases.

Over 16,000 women 15-34 years of age were reported to be living with AIDS in the United States at the end of 1999. These women are of childbearing age and in the years of highest fertility. States with HIV

case surveillance data are better able to target programs and services to these women to enhance efforts to further reduce transmission to their newborns.

The 32 areas that conduct name-based confidential HIV infection surveillance of adults and adolescents reported an additional 15,190 women in this age group living with HIV infection. In most states with HIV surveillance, the number of infected women who have not developed AIDS exceeds the number of women with AIDS. These numbers indicate the current burden of HIV morbidity and the substantial need for medical and social services for these women, currently and in the future.

The number of young women living with HIV in the South is quite striking. A large number of HIV-infected women reside in states that do not have HIV surveillance, and undoubtedly there are many infected women who have not been tested. Thus, the HIV numbers are underestimates of the true HIV-infected population.

Perinatal AIDS cases rose rapidly through the 1980's, peaked in 1992 (N=909), and then declined 81% following PACTG 076 and the PHS recommendations to a low in 1999 (N=171). Declines occurred in all racial and ethnic groups, where the majority of cases occur in African American and Hispanic children, and in all age groups. Some of the most recent declines may also be due to improved therapy of HIV-infected children. Reflecting recent perinatal prevention efforts, the largest declines occurred earliest among infants and also those diagnosed at 1-5 years who were born in more recent years.

Trends declined in all regions. CDC estimates that there were1,200 HIV-infected children born in 1992, which decreased to an estimated 400 and less born in recent years. Of prenatally- acquired AIDS cases born in 1997-1998 and reported to CDC, one-third involved mothers who were tested for HIV after the child's birth; only 13% of these women received ZDV in pregnancy, 23% of the infants received ZDV neonatally, and 60% of the infants were not tested for HIV in the first 2 months of life. Thus, although the successes are dramatic there are still missed opportunities for prevention.

Can More Cases Be Prevented?

Perinatal transmission of HIV can be prevented by interventions during the prenatal, perinatal, or postnatal periods. However, these interventions cannot be successful unless the HIV-infected woman is in prenatal care, is offered and accepts an HIV test, is offered and accepts ZDV, and adheres to the drug regimen. In addition, providers and clients are responsible for adherence to regimens during the intrapartum and neonatal periods, and the mother and infant must receive follow-up care. Mothers must also avoid breast-feeding.

It is important to evaluate all available surveillance data at the local, state or national level to characterize the perinatal HIV epidemic and to target and evaluate prevention efforts. This includes data on:

- prenatal care:
  - general population: birth certificates, Pregnancy Risk Assessment Monitoring System (PRAMS)
  - HIV-positive women: enhanced perinatal HIV surveillance
- HIV counseling and testing:

- all pregnant women: birth certificates, PRAMS, audit of hospital birth records–Emerging Infectious Disease Program (EID) sites
  - HIV-positive women: enhanced perinatal HIV surveillance
- use of antiretroviral therapy:
  - enhanced perinatal HIV surveillance, Serosurvey of Childbearing Women (SCBW)
- outcome of child
  - enhanced perinatal HIV surveillance
- other sources: Medicaid data, Supplement to HIV/ AIDS Surveillance (SHAS), HIV counseling and testing data, Adult Spectrum of Disease (ASD), Pediatric Spectrum of Disease (PSD).

Analysis of data from the Behavioral Risk Factor Surveillance System (BRFSS), a telephone interview survey of a random sample of adults aged 18 years and older, showed that the proportion of pregnant women tested for HIV increased from 1994 to 1996 (42.6% to 53.1%), and then again from 1997 to 1998 (51.7% to 55.9%). The proportion of pregnant women who reported pregnancy as the reason for their test increased from 60% in 1994 to 84% in 1999. Pregnant women were more likely to be tested if they lived in the South, were not working, were 18- to 24-years-old, never married or had health insurance.

Preliminary data from a birth audit conducted on a random sample of maternal delivery records for 1998 and 1999 births from three states (Georgia, Minnesota, and Connecticut) in the Emerging Infectious Program Network indicate that, in contrast to extremely high testing rates documented for syphilis, testing for HIV was much less complete and varied by state, from less than 40% in Connecticut to over 60% in Georgia.

The pregnancy risk assessment monitoring system (PRAMS) is an ongoing population-based surveillance system of women who recently delivered a live-born infant. The sample is drawn from birth certificates 2-4 months after birth; women are mailed a questionnaire and followed up by telephone. Responses from mothers who sought prenatal care during their pregnancy indicated that offers of testing and counseling for HIV varied by state (60%-80%), but that a substantial proportion of mothers did receive prenatal HIV test counseling and a high proportion of mothers accepted the test (1998 estimates available for 11 states).

For the perinatal HIV guidelines evaluation project, 1,362 women in four states were interviewed 24-48 hours postpartum. Although 82%-92% were offered an HIV test, the proportion tested differed dramatically by site (46%-86%; 75% overall). There was a higher proportion tested among those offered the test as well as among those whose provider recommended the test.

Pregnancy rates in HIV-infected women enrolled in the adult and adolescent spectrum of disease project (ASD) did not change significantly during 1996-1998 compared with 1991 through 1995. However, pregnancy rates did increase significantly from 1996 to 1998. Women who received HAART were more likely to become pregnant compared to women who were receiving other antiretroviral therapies. Pregnancy rates were highest among women 15-24, and were higher for black women than white women.

Data on 1,431 HIV-infected mothers who gave birth in 1995-1997 in the seven states that conducted enhanced perinatal surveillance indicate that 13% had no prenatal care and an additional 9% had only

1-2 visits; 2% of women in the general population had none or only 1-2 visits. Women who use illicit drugs in pregnancy are at high risk for not receiving prenatal care. In these seven states in 1995-1997, 83% of HIV-infected mothers with no prenatal care used illicit drugs in pregnancy, compared with 23% of those with 3 or more prenatal care visits. Mothers with less prenatal care were also less likely to have received prenatal ZDV, but rates differed markedly among states.

Once in prenatal care, women need to be offered and need to accept HIV testing. States with enhanced perinatal HIV surveillance have data on 88% of HIV-positive women delivering in those states. Thus, we analyzed trends in maternal HIV testing of the reported mothers in these states. The proportion diagnosed with HIV before giving birth increased from 84% in 1993 to 89% in 1996 and remained stable in 1997. The percentage of those tested after birth declined, but 4%-5% of women continued to be tested at delivery, and 6% of the mothers were tested after birth in 1996 and 1997. Data from states with HIV surveillance also indicate an upward trend between 1994 (76%) and 1999 (92%) in percentage of women diagnosed prior to giving birth.

Of 8,306 HIV-exposed deliveries in 33 states with HIV surveillance, the percentage of deliveries by cesarean section increased from around 15% in the first half of 1994 to nearly 50% in the first half of 2000. Data reported for over 8,500 prenatally-exposed children born to HIV-positive mothers diagnosed with HIV before or at birth demonstrate rapid uptake of recommended ZDV therapy from 1994-1996 with a relative leveling since 1997. Receipt of any component of the recommended ZDV regimen increased from 37% of children born in 1994 to 90% in 1997 and then leveled; receipt of prenatal ZDV increased from 30% in 1994 to 71% in 1996 and then leveled. Increasing numbers of HIV-infected women are receiving combination therapy during pregnancy for their own health: 39% in 1998 and 52% in 1999 and almost 60% in the first half of 2000. Between 1994 and June 2000, only 0.9% of women refused ZDV in pregnancy; of these, 77% accepted ZDV treatment for their newborns. In recent years, only 15%-17% of HIV-infected pregnant women had no antiretroviral therapy.

The increasing proportion of HIV-infected mothers and their infants who have received any ZDV has resulted in declining perinatal HIV transmission and a dramatic decline in AIDS cases among these infants. Data from the 33 states reporting HIV infection demonstrate declines in perinatal HIV infection rates. Of children first evaluated for HIV at less than two months of age, 22% were infected in 1993; this percentage declined to 9.5% in 1996, then 7% in 1998, to an all-time low of 4.4% in 1999. Follow-up still continues. Based on data from states with enhanced perinatal surveillance, receiving all three components of ZDV was associated with a 68% reduction in transmission of HIV to the infant.

Despite dramatic declines, cases of perinatal HIV infection continue to occur, mostly because of missed opportunities for prevention. We examined 227 HIV-infected children born from1995 to 1997 in the states with enhanced surveillance. Our findings:

- prenatal care
  - 14% had none; 26% unknown
  - of those who received care, 14% had <2 visits
- maternal HIV testing
  - 20% tested after delivery
  - 7% tested at delivery
- antiretroviral therapy

- of mothers tested before delivery and who had received prenatal care, 22% were not prescribed prenatal ZDV
- 29% had all 3 prevention interventions: prenatal care, HIV test before birth, prescribed prenatal, intrapartum and newborn ZDV.

Current Trends and Concerns

Prenatally-acquired cases of AIDS have declined dramatically since peaks in 1992-1994. Among children 1-4 years of age, annual rates of death per 100,000 population from AIDS increased from 1987 to 1995 and then declined dramatically through 1998. Based on increasing survival, we estimate that approximately 10,000 children are living with perinatal HIV infection, of whom approximately 2,200 are adolescents. Targeted education and prevention strategies surrounding sexual health, prevention of ongoing sexual transmission and improved adherence with complex treatment regimens are critical.

An ongoing concern is the potential toxicity of drugs administered in the perinatal period. Nucleoside reverse transcriptase inhibitors (NRTI) have known toxicity to the mitochondria: ZDV and other NRTI's inhibit mitochondrial DNA polymerase gamma. In February 1999, two HIV-uninfected infants prenatally- exposed to ZDV + 3TC were reported to have died of progressive neurologic disease associated with mitochondrial dysfunction (*Lancet* 1999;354:1084-9). They were both one-year old.

A perinatal safety review working group examined all deaths among HIV-exposed children who died at less than 5 years of age in five U.S. cohorts, including those reported through pediatric HIV surveillance. Among over 20,000 children born to HIV-infected women, over half of whom had been exposed to NRTI's, 223 died. None died of mitochondrial dysfunction consistent with those cases presented by the French investigators. However, innovative surveillance strategies are needed to follow potential adverse events from perinatal antiretroviral drug exposure.

Conclusion

The data I have presented show rapid implementation of Public Health Service guidelines and a recent leveling in rates of receipt of antiretroviral therapy and of prenatal HIV testing. Substantial declines in prenatally- acquired AIDS and perinatal HIV infection rates were coincident with increasing ZDV use. Missed opportunities occurred among high risk women: those without prenatal care, particularly illicit drug users, and those who present in labor with unknown HIV status.

In order to eliminate perinatal HIV transmission, in addition to continued sustained efforts, intensive new programmatic efforts are needed to reach these high-risk HIV-infected women, including public information campaigns and outreach to increase access to prenatal care. Future efforts should include education and training of providers to offer prenatal HIV counseling and voluntary testing as a standard of care and operational research to implement rapid HIV testing and institution of ART during the intrapartum period for women without prenatal care. Enhanced perinatal HIV surveillance, expanded to 22 states, will help target these efforts and will help evaluate the extent that intensified prevention programs contribute to reduced transmission. Innovative surveillance strategies are needed to monitor antiviral resistance and potential toxicities. Clearly, prevention of HIV infection in women is critical. Most importantly, a global effort to address the ever growing perinatal HIV epidemic in the rest of the world is urgently needed, both to extend benefits seen in U.S., and to develop effective strategies for

resource-poor countries.

Current Treatment Approaches for HIV-infected Pregnant Women: Progress and Challenges

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Elective cesarean section and combination antiretroviral therapy are new approaches for treating HIV-infected pregnant women. However, the morbidity associated with cesarean section, the side effects of antiretrovirals, and the provision of effective long-term contraception for women who are not planning another pregnancy present ongoing challenges.

Progress

A breakthrough study by the European Mode of Delivery Collaboration ("European randomized mode of delivery trial: elective cesarean at 38 weeks vs. vaginal delivery." *Lancet* 1999;353:1035-9) indicated a significantly lower transmission rate ((1.8%, N=170) in those HIV-infected pregnant women undergoing elective cesarean section compared with those (10.5%, N=200) who delivered vaginally. Not all patients in the study received antiretroviral therapy.

The International Perinatal HIV Group did a meta-analysis of 15 prospective cohort studies on mode of delivery and the risk of vertical transmission of human immunodeficiency virus (*New England Journal of Medicine* 1999 Apr 1;340(13):977-87). The meta-analysis revealed a 50% reduction in transmission in women undergoing cesarean sections (antiretroviral treatment of women in these studies was unknown). Women receiving antiretroviral therapy and undergoing cesarean sections showed an 87% reduction in transmission (2%–7% transmission rate).

This meta-analysis resulted in the following ACOG Committee Opinion (Number 219, August 1999):

- All HIV-infected women should be offered scheduled cesarean section at 38 weeks.
- Woman's choice whether to deliver by cesarean section must be respected.
- Combination drug regimen may reduce the risk of transmission to such low levels that cesarean section may not offer additional benefit.

There are several potent regimens of combination antiretroviral therapy (two nucleoside analog reverse transcriptase inhibitors plus a potent, bioavailable protease inhibitor). However, except for zidovudine, we do not have much information on the toxicity of these agents. Many effectively treated persons will demonstrate a rapid rate of decline in plasma HIV RNA concentrations and then a more gradual phase of decline to below detectable levels by approximately 8 weeks after initiation of combination therapy (*MMWR* 1998;47[No. RR-5]).

Recent studies (Garcia PM, et al. *New England Journal of Medicine* 1999 Aug 5;341(6):394-402; Mofenson LM, et al. *New England Journal of Medicine* 1999 Aug 5;341(6):385-93; and Clarke SM, et al. *International Journal of STD & AIDS* 2000 Apr;11(4):220-3) have examined the relationships between viral load, combination therapy, and the vertical transmission of HIV. Some of the findings were:

- There does not appear to be threshold below which lack of transmission can be assured.
- Rate of transmission in women with undetectable viral loads was similar to those who receive ZDV and undergo elective cesarean section.
- Transmission occurred in 1 of 364 women with viral load less than 500 copies per mL.
- Transmission occurred in 6 of 461 women who received 2 or more antiretrovirals.

Challenges

There seems to be increased morbidity associated with cesarean section vs. vaginal delivery. JS Stringer, et al. *(JAMA* 1999 May 26;281(20):1946-9) suggest there is cause for restraint when considering elective cesarean section:

- Associated with protective effect in some observational studies but not others.
- In the independent meta-analysis previously cited, approximately 62% of mothers did not receive antiretroviral therapy.
- Results from meta-analysis cannot substitute for a randomized controlled trial (RCT).
- Meta-analysis of even RCT will predict an effect that will later be discredited by large randomized trials as often as 35% of the time.

The European RCT of mode of delivery in HIV-infected pregnant women (previously cited) did not find any major morbidity in the study or control population, but fever was more likely in those undergoing cesarean section (6.7% vs. 1.1%). DH Watts, et al. (*American Journal of Obstetrics & Gynecology* 2000 Jul;183(1):100-7) reported that: "Endometritis and wound infection occurred more frequently among human immunodeficiency virus–infected women after cesarean than among women undergoing vaginal delivery; however, complication rates overall were within the range reported in human immunodeficiency virus–negative women." In addition: "Any peripartum infection occurred among 16 (18%) of those with a CD4 count of $<200/\mu L$ and 43 (13%) with a CD4 count of $\geq 200/\mu L$ ($P = .17$)."

The safety of antiretrovirals for pregnant women must also be considered. In 13 monkeys exposed to the frequently used drug efavirenz (sustiva), 3 had offspring with birth defects (1 cleft palate, 1 microphthalmia, and 1 anencephaly). In 1998 the FDA issued an alert indicating that sustiva should not be used in pregnant women.

Since Dr. Mofenson has already discussed the potential mitochondrial toxicity of antiretrovirals, I will skip this topic.

On January 5, 2001, Bristol Myers Squibb issued the following caution on the combination of stavudine and didanosine:

- 3 cases of fetal lactic acidosis have been reported:

2 pregnant: one antepartum and one postpartum
- 2 infants died: intrauterine fetal death at 32 weeks, and neonatal death at 36 weeks, after emergent cesarean section
- several nonfatal cases of pancreatitis with or without lactic acidosis or hepatic failure in pregnant women have been reported
- the combination should be used with caution during pregnancy; recommended only if benefit outweighs risk.

About 60% of women who have a repeat pregnancy report that the pregnancy was not planned. Thus long-term contraception for women who are not planning another pregnancy remains an important challenge. Potential methods of postpartum conception that should be considered include: condoms, Depo-Provera, Norplant, tubal ligation, oral contraceptive pill, barrier method, morning-after pill, and natural family planning.

In summary, potential prevention strategies for risk factors for perinatal HIV transmission are (modified from *Clinical Obstetrics and Gynecology* 1996;39:386-95):

Risk Factors for Perinatal HIV Transmission and Potential Prevention Strategy

Risk Factor	Prevention Strategy
Maternal disease status	Antiretroviral therapy
Obstetrical determinants	Elective cesarean section Avoid rupture of membranes Avoid invasive procedure

Finally, insure that all HIV-infected pregnant women receive long-term therapy and follow-up.

From the Perspective of Women

Roslynn Howard-Moss
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From my experience as an HIV-positive woman and as a participant in the 076 clinical trial, I have found that the issues pertinent to health care providers are not always the issues at the forefront for HIV-positive women. This is not to say these issues should not be addressed, but they may need to be addressed in a different manner. The clinical and social expectations we have of these women may not be reachable, but supporting these women is paramount in providing the best clinical care we can. Health care providers, including myself, have their own biases when it comes to HIV-positive pregnant women. Providers should not be judgmental about this, but focus on what will help most.

I am privileged and honored to be part of a great support team for HIV-positive women at Johns Hopkins. We have found that it is of great help to connect HIV-positive pregnant women with women who have already been through this experience. It greatly enhances acceptance of the clinical strategies of providers by opening these women up to the fact that they are not the only ones who have had to deal with this, and by connecting them to a community of people who will be there to help them when the clinical staff can't be, for example, when they are having adverse reactions to their medications or when they need help with the children because they are feeling too sick to deal with them. The WIN study has helped show just how many people in the HIV-positive community are willing to help and dedicate their lives to helping others who are positive.

It's important that HIV prevention efforts in this area address the whole community. That is, men and their role in transmission of HIV to infants need to be addressed. It is not only a woman's problem. For example, we have found that offering counseling and testing to men who accompany women to GYN clinics (before the women get pregnant) has been a very successful strategy. The belief that you can't reach low-income African American males is simply not true; I can say that when I have approached these men, I have had a 97% acceptance rate (it's true we use tests other than the blood test).

The hardest-to-reach women are not those who know they are HIV-positive, but the women who get less than optimal prenatal counseling and testing or who can't imagine that they might possibly be infected or could have an infected baby. I would like to see guidance and training for providers who offer HIV counseling and testing because it is not like other STDs.

I would also like to see incorporated into counseling and testing sessions an overview of what is currently happening with HIV. Many women in minority communities feel that, since there is no cure for HIV infection, nothing can be done. We must reach them with the message that there is no reason for total despair and much can be done for them and for their unborn baby.

Programs targeted to HIV-infected pregnant women can be successful as is evidenced by our own program at Johns Hopkins. We have had 100% of our women accept some kind of therapy; some as late as 34 weeks, but most beginning at 14-20 weeks. This is not only because of the efforts of the 5 people working on support, but also because we "employ" others to help us, even if it is just to make a phone call to these women (sometimes the women are more willing to talk on the phone than have a face-to-face interview). Because of our high rates of acceptance of testing and treatment, since 1994 we have had only one baby infected whose mother has come through our program (the mother already had an herpes infection when she enrolled).
Finally I want to thank this group for the efforts it has made and the progress it has made which gives hope and inspiration to those of us working on the front lines.

Susan Wheeler
Positive PEACHES, Inc.
Conyers, Georgia

I also want to emphasize the importance of helping HIV-infected pregnant women find others who have faced this situation. I think it would have been helpful to me back in 1990 when I was having to make

decisions and deal with the fact that I was a pregnant woman infected with HIV.

It is also important for health care providers to listen to and respect women's desires and choices. Their views, especially their views on their own health condition, need to be taken seriously. I know my health care provider back then would not listen to my wish to take AZT. Today, I would not let my health care provider have the final say.

You need to respect women and their opinions and what they want. You or I may be infuriated with a woman who does not want therapy or a c-section, but it does no good to try to coerce them, because they may just not be ready to hear it. If later, they regret not listening to you, don't take an I-told-you so attitude; just go forward from that point in caring for them. I also think that women have more or, at least, different side effects than men. Women know their own bodies and what they're going through; providers need to respect them and listen to them.

If women are not willing to do what you think is best for them clinically, you should put them in contact with someone who has already been through all this. Again it could be just phone contact; they need not ever meet. But there will always be someone there for them. I think it would have helped me; there is just a sense that you can trust someone more who has been what you're going through.

General discussion: Where there is a conflict between the pediatrician's wishes for the woman and her own wishes, it is best to refer her to a different "messenger;" maybe she will hear the message then.

The community needs to be brought in early in dealing with an HIV-infected woman–there is a lot of stigma surrounding these women. Mentors are often needed for these women; providers may be looking down on them or in other ways not respecting them–women often pick up on this. Also there may be a lot of mistrust of the government and the medical establishment in some of these communities. Bringing a CBO or a non-governmental provider into the situation may help.

Our belief is that the child should not be taken away from the mother unless there is simply no other option for getting the child treated. In that case, the child should be taken into protective services.

Communication with HIV-infected pregnant women is extremely important. Some models that have proved effective are: peer-based counseling and support; programs that empower the woman and others in the community, e.g., to participate in the legislative process; and programs that help the woman to feel good about herself and the future. Stress can be an extremely destructive force in their lives.

Welcoming Remarks–Day 2

Helene Gayle
Director, National Center for HIV, STD, and TB Prevention
Centers for Disease Control and Prevention

There has been dramatic progress in reducing perinatal HIV transmission in the U.S. since 1994 when the successful clinical trial (PACTG 076) results were first announced. Women are being offered voluntary counseling and testing more routinely, and zidovudine (ZDV) use for prevention of mother-to-child transmission has also increased. Perinatally-acquired AIDS has decreased dramatically–down 81% since 1993.

This progress is related to a number of factors. In addition to ZDV regimens for mothers and infants, women are also receiving combination antiretrovirals for their own care during pregnancy. At many referral centers, perinatal transmission rates as low as 1%-3% are being reported for these women. Obstetrical interventions to reduce infant exposure during labor and delivery, i.e., elective c-sections, are also being employed.

However, gaps still remain. Some women still do not receive antenatal care; some women who do receive antenatal services are not offered voluntary counseling and testing; some HIV-infected women who are identified during pregnancy do not receive antiretrovirals either for their own care or to prevent perinatal HIV transmission; and some babies still continue to be infected. Thus, congressional funding of CDC under the Ryan White Care Act for this perinatal HIV prevention initiative remains important.

This meeting brings together a variety of important public health programs both at the state and national level. At the national level, CDC is working closely with NIH, HRSA, SAMSHA and national health care provider organizations to implement perinatal HIV prevention programs. This includes joint efforts in the development and implementation of the USPHS guidelines for counseling and testing; for reducing perinatal HIV transmission; and for women's health care and treatment. Here at CDC, the HIV prevention staff have linked with the surveillance and epidemiology staff to assist you in your state efforts. At the state level, HIV prevention, maternal and child health, Medicaid, substance abuse, and other relevant programs are working together to provide perinatal HIV prevention services.

At all levels, it is critical that mother-infant HIV prevention activities be integrated with other HIV prevention efforts. This initiative does so by bringing lessons learned from perinatal HIV prevention successes as well as from other HIV prevention successes to the task of reaching those women and infants who may not have been reached by other HIV prevention efforts.

We want to thank our partners at NIH including NIDA, NICHD, NIAID, as well as colleagues at SAMSHA and HRSA, for being a part of the coordinated Public Health Service approach to reducing perinatal HIV transmission, and for supporting treatment for HIV-infected women, children and youth. We also appreciate the continued collaborations with our partners at NASTAD and the national health care provider organizations.

We look forward to your continued progress and feedback both during the meeting and over the next

year in this critical public health effort. Thank you for your dedicated work on behalf of women and children. We pledge CDC's continued support and technical assistance as we move ahead together to maximally reduce and potentially eliminate all new cases of perinatal HIV transmission in the U.S.

What's New in Perinatal Research? U.S. and International Update

Marc Bulterys
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[*Note: A number of the ideas in this presentation are also in a paper which will be published shortly in a supplement to the journal* Trophoblast Research.]

U.S. Update

The incidence of perinatally-acquired AIDS in the United States has shown an 81% decline as of June 2000 (reports through December 2000) from its all-time high in 1992. The Women and Infants Transmission Study (WITS) and other studies have demonstrated that the decline in perinatal transmission in the study population is associated with use of perinatal antiretroviral treatment, especially since 1994.

A. Dorenbaum reported the results of PACTG 316 at the 8th Conference on Retroviruses and Opportunistic Infections (Abstract LB7) in February of this year: "Among HIV-infected women who receive prenatal care and who are treated with standard ARV prophylaxis (generally combination therapy), the risk of perinatal transmission is low (1.5%; 95% CI 1.0-2.7%). Administration of the 2-dose NVP prophylaxis regimen did not further reduce transmission in this setting."

We have seen an increase in the percentage of HIV-infected pregnant women undergoing cesarean section in the U.S. to around 44% in 2000 (The Pediatric Spectrum of Disease study), a practice which seems to decrease risk of perinatal transmission. This percentage is still lower than that seen in Europe and Brazil.

Reduction of perinatal HIV transmission below 1% in the U.S. seems feasible. The remaining U.S. groups at risk for perinatal HIV transmission include:

- late presenters without prenatal care
- women seen in antenatal care but not offered voluntary counseling/testing due to perceived low risk
- HIV-infected pregnant women who were prescribed but did not take antiretrovirals
- unexplained "failures."

Determining the timing of perinatal HIV infection is of great clinical relevance for implementing cost-effective prophylaxis. A recently published study (Kourtis AP, et al. *JAMA* 2001; 285:709-12) proposes a model for the approximate temporal distribution of mother-to-infant transmission (in non-breastfeeding populations) based on findings from recent studies, arguing that most HIV infections occur very late in gestation. Estimations suggest that most transmission occurs during the last few days of pregnancy.

This table provides a summary of current knowledge on factors affecting mother-to-child HIV-1 transmission.

Known risk factors	**Factors for which evidence is suggestive but not conclusive**
High maternal viral load	Genetic factors
Viral genotype/phenotype	Immature immune system in infant
Advanced maternal HIV disease	Increased viral strain diversity
Low CD4 count or percent	Maternal neutralizing antibody
Vaginal delivery	Illicit drug use during pregnancy
Duration of membrane rupture > 4 hours	Frequency of unprotected sexual intercourse
Premature delivery (< 37 weeks)	Multiple sex partners during pregnancy
Breastfeeding	Maternal nutritional status
	Anemia during pregnancy
	Cigarette smoking
	Chorioamnionitis
	Abruptio placentae
	Placental *P. falciparum* infestation
	Syphilis and other STD
	Fetal scalp electrodes
	Episiotomy and vaginal tears

Of the known risk factors, how important is maternal viral load?

- Maternal HIV-1 RNA level is strongly correlated with risk of transmission.
- RNA level near the time of delivery is an important predictor of transmission even among ARV-treated women.
- Most studies do not find a threshold below which no transmission occurs.
- The 076 zidovudine regimen appears to be protective at all levels of maternal RNA (ACTG 076 findings).

Transmission rates by plasma viral load at time of delivery were studied in Bangkok, Thailand by N. Shaffer, et al. (*Journal of Infectious Diseases* 1999 Mar;179(3):590-9). Although risk is multifactorial, they found that "high maternal virus load at delivery strongly predicts transmission."

A recently published meta-analysis (Ioannidis JP, et al. *Journal of Infectious Diseases* 2001; 183(4):539-45) determined that transmission in women with RNA<1000 copies/ml was lower with

antiretroviral treatment, cesarean section, greater birth weight, and higher CD4 cell count The authors concluded that:

- Perinatal HIV-1 transmission occurs in only 1% of treated women with RNA virus loads <1000 copies/ml at delivery.
- Antiretroviral treatment reduces the risk of transmission even in women with RNA < 1,000 copies/ml at delivery and when adjusting for potential confounders. This protective effect seems to operate above and beyond the lowering of maternal viral load.

Host genetic factors and perinatal HIV transmission is currently a topic of great interest. What do we know about it?

- Immunogenetic mechanisms facilitating protection of approximately 75% of HIV-exposed infants are still poorly understood.
- Data from Kenya suggest that Class I HLA mother-infant concordance is associated with increased risk of transmission (MacDonald KS, et al. *Journal of Infectious Diseases* 1998 Mar;177(3):551-6); also independent effect of HLA supertype A2/6802 (MacDonald KS, et al. *Journal of Infectious Diseases* 2000 May;181(5):1581-9).
- Association of Class II HLA homozygocity with transmission as well as disease progression was shown in PACTS case-control study (as yet unpublished data)
- Polymorphisms in the regulatory regions of CCR5 may also influence transmission (Kostrikis LG, et al. *Journal of Virology* 1999 Dec;73(12):10264-71).

Maternal sexual behavior may be related to mother-to-child HIV-1 transmission. In two African cohort studies, investigators reported a higher risk of vertical HIV-1 transmission related to unprotected sexual intercourse with multiple partners (Bulterys M, et al. *AIDS* 1993 Dec;7(12):1639-45; Lallemant M, et al. *AIDS* 1994 Oct;8(10):1451-6). In Italy, mother-to-child transmission was more frequent among concordant HIV-positive mother-father couples (Galli L, et al. *Pediatric AIDS and HIV Infection: Fetus to Adolescent* 1993; 4:425-8.). In New York, frequency of unprotected intercourse during pregnancy was strongly associated with HIV mother-to-child transmission (Matheson PB, et al. *AIDS* 1996 Sep;10(11):1249-56).

In an article entitled "From biology to sexual behavior--towards the prevention of mother-to-child transmission of HIV," (*AIDS* 1996 Sep;10(11):1287-9), I and my co-author argued that promotion of safer sexual practices and improved treatment of STD may be widely applicable public health strategies to reduce mother-to-child transmission. Unsafe sexual practices and poor or no treatment of STDs might increase risk of vertical transmission through such plausible pathophysiological mechanisms as: a) HIV-1 concentration or strain diversity; b) inflammation of the cervix or vagina by microabrasions or sexually transmitted infections; and c) chorioamnionitis or reduced placental integrity.

Another research question of current interest is whether mother-to-child HIV-1 transmission rates are decreasing over time. Even in the absence of antiretroviral prophylaxis, mother-to-child transmission rates appear to decrease over time in many locations (e.g., Bangkok, Kampala, Miami, Nairobi, New York City). Possible explanations as to why the highest mother-to-child transmission rates occur during the early years of epidemic HIV-1 spread include: a) bias due to differential infant follow-up; b) changes in obstetric practice; c) changes in the proportion of women with advanced HIV disease or incident HIV

infection; d) host genetics--women at highest risk for mother-to-child transmission become infected first; and e) the possibility of viral attenuation over time.

What does recent research tell us about the role of neonatal antiretroviral prophylaxis in reducing the risk of perinatal HIV transmission? Studies from sub-Saharan Africa and New York state and data from CDC's Perinatal AIDS Collaborative Transmission Study (PACTS) allow us to draw the following conclusions:

- Neonatal prophylaxis starting in labor through 1st week of life reduces transmission in breastfeeding settings.
- Intrapartum ZDV/3TC alone is not sufficient.
- 2 neonatal doses of PMPA can protect newborn macaques against SIV infection.
- 6 weeks of neonatal ZDV can be effective in non-breastfeeding settings, if started within 12-24 hours after birth.
- Optimal duration of prophylaxis for breastfed and non-breastfed infants remains unclear.

CDC's Mother-Infant Rapid Intervention At Delivery project (MIRIAD) will start a new protocol in 5 U.S. cities (Atlanta, Chicago, Miami, New Orleans, and New York) as soon as IRB review is completed. The objectives of the MIRIAD project are to:

- evaluate innovative approaches to counseling and voluntary rapid HIV testing for women in labor with unknown HIV status
- assess feasibility of obtaining informed consent during labor or soon after birth
- describe barriers to HIV testing and reasons for lack of prenatal care
- assess rapid delivery of ARV prophylaxis to late presenters
- evaluate neonatal therapy adherence; and receipt of post-natal care for women identified as HIV-infected.

Update: International Perinatal HIV Research Progress

Short-course antiretroviral trials show that peripartum ZDV and nevirapine (NVP) regimens remain efficacious despite ongoing transmission through breastfeeding. However, recent studies have detected the presence of maternal resistant mutations to NVP and 3TC at 6 weeks postpartum and NVP resistance in infants who became infected despite NVP prophylaxis.

Embree, et al. (*AIDS* 2000 Nov 10;14(16):2535-41) identified the following clinical risk factors for HIV-1 transmission through breastfeeding in Nairobi:

- primary HIV-1 infection during lactation
- high plasma and breast milk viral load
- prolonged duration of breastfeeding (>15 months)
- clinical and subclinical mastitis, breast abscesses
- thrush in the infant.

Also in Nairobi, GC John, et al. (*Journal of Infectious Diseases* 2001 Jan 15;183(2):206-12) identified

correlates of early vs. late infant HIV-1 infection:

Early Infection (<2 months of age):
Viral load (plasma RNA, cervical or vaginal DNA)
Cervical or vaginal ulcers
CD4 count <200
Prematurity
Breastfed
Bleeding nipples

Late Infection (> 2 months of age):
Maternal plasma RNA >43,000
Mastitis
Breast abscess.

Several clinical trials on reducing rates of HIV transmission through breastfeeding are being planned in Africa and India. These will include: infant ARV prophylaxis trials; vaccine and passive immune trials; exclusive breastfeeding; and early and abrupt weaning. However, a soon-to-be-published study (in *Lancet)* showed that mortality among HIV-infected women in Nairobi was significantly higher in breastfeeding than in formula-feeding women.

Implementation of international perinatal HIV prevention faces many challenges:

- sharp increases in seroprevalence during adolescent years, particularly among female youth
- high HIV prevalence among pregnant women
- inadequate antenatal voluntary counseling and testing (VCT) infrastructure
- reversal, related to HIV, in infant survival gains
- breastfeeding transmission
- competing health priorities in face of scarce resources.

The magnitude of the problem is enormous. An estimated 620,000 children were newly infected with HIV during 1999; 515,000 of these in sub-Saharan Africa.

CDC sponsors a number of perinatal HIV prevention activities in Kenya:

- implementation of single-dose NVP at Kisumu Provincial Hospital, Nyanza Province
- planned expansion to local district health centers and traditional birth attendants in Asembo Bay, Nyanza
- follow-up of mother-infant cohort to assess the impact of placental malaria on perinatal HIV transmission
- an integrated approach to improving child survival
- technical assistance to the Ministry of Health (LIFE initiative).

A successful international model of perinatal HIV prevention is found in Thailand. Elements of this successful model include:

- built on short-course ZDV trial results
- government commitment
- well-organized antenatal infrastructure including VCT
- successful pilot projects being expanded to national level
- next steps include identifying women needing treatment.

In summary, the main research challenges in global prevention of perinatal HIV infection are:

- primary prevention of HIV among youth
- decreasing transmission through breast milk, and
- operational research on implementation of short-course ARV interventions.

Conclusion

Two perinatal HIV-1 epidemics exist. There has been dramatic progress in the U.S. and Europe in research and implementation. There has also been progress in international research, but there are major implementation challenges in the developing world. Integrated maternal-and-child-health approaches to improve child survival are urgently needed.

Preventing Perinatal HIV in New York City: A 20-Year Public Health Perspective

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The number of perinatally acquired AIDS cases reported in New York City by year of birth has declined dramatically from a peak of 176 cases in 1990 to 1 case in the 1999 birth cohort. This decline is attributable to:

- lowering of HIV transmission rate,

- fewer HIV-infected women giving birth, and
- delay in AIDS due to improvement in medical therapy.

Trends in Perinatal HIV in NYC

The New York City Department of Health has monitored HIV-exposed infants since 1989 at 22 pediatric HIV care sites through the Pediatric Spectrum of HIV Disease (PSD) study and through its HIV/AIDS surveillance system. The New York State Department of Health has collected supplemental data on HIV-exposed infants since 1996.

The New York State Department of Health has monitored HIV positivity of newborns through heelstick testing since 1988:

—1988-96: Blinded serosurvey
—1996: Serosurvey results offered, majority of mothers received results
— 1997-00: Universal linked testing of newborns (with supplemental data collection).

In August 1999, a rapid testing program began. A rapid test was offered to women presenting in labor who had no documented HIV test result. It was mandatory for the infants of women who declined the rapid test for themselves.

Data collected by NYC (since 1989) and by NYS (since 1996) include: HIV infection status of HIV-exposed newborns; prenatal care; prescription of ZDV and other ARVs prenatally, intrapartum, and neonatally; mode of delivery; and maternal risk factors. These data indicate that the number of HIV-positive pregnant women delivering in New York City has declined from more than 1500 in 1991 to 770 in 1999 and that the estimated number of HIV-infected infants has declined from 302 to 92 in that same period.

When we look at a subset of these children (those picked up by NYC DOH perinatal exposure surveillance at 22 hospitals), infection rates in children evaluated for HIV before 3 months of age declined from 20%-25% in 1992-1994 to less than 10% in1998- 2000. Infection rates began to decline even before 1994, when prophylaxis began. However, these are not population-wide data and the HIV status of many in our data base is still indeterminate.

However, when we look at state data on *all* HIV-exposed births in NYC in the last 3 years, we can confirm that the citywide transmission rate in 1999 is, in fact, an amazingly low 7% (58 out of 782 HIV-exposed births). Because of the intense follow-up and free PCR testing at state labs, the HIV status of children in this database remains indeterminate in only a few cases.

Successes in Prevention

There are several steps that can be taken to prevent perinatal HIV transmission:

- prevention of HIV infection in women
- quality care for HIV-infected women
- prenatal care

- prenatal evaluation for HIV
- prescription of antiretrovirals for perinatal prophylaxis
- delivery by elective cesarean section.

Data from our 22 pediatric HIV care sites in NYC (1996-1999) indicate that 5%–10% of HIV-infected pregnant women receive no prenatal care. An additional 10% get no prenatal HIV test, although that percentage is improving. Fifty percent of women in prenatal care got multiple ARVs during pregnancy in 1999; 15% got none; 25% got monotherapy with ZDV. We need to find out who the women in these last two groups are and why they did not receive optimal therapy.

If we look at antiretroviral use and infant HIV infection status from these same data, we note that use of ARV and ZDV prenatally plus intrapartum and neonatal ZDV resulted in a 1% infection rate in infants; and use of prenatal, intrapartum and neonatal ZDV resulted in a 6% infection rate. Infants who received neonatal ZDV only (started within 24 hours of birth) were infected at rates (12%) half those (24%) of infants not treated neonatally and whose mothers received no ARVs (V. Peters, et al. *8th Conference on Retroviruses and Opportunistic Infections*, February 2001, Abstract No. 703).

Use of cesarean section among HIV-infected women is also increasing in NYC (20% in 1996-1998; 38% in 1999). Chart review data indicate most of the increase is due to deliberate use of elective c-section for HIV prevention.

Can Mother-to-Child HIV Transmission Be Eliminated in NYC?

Elimination of perinatal HIV in NYC seems possible. Remaining obstacles include:

- lack of prenatal care
- HIV not identified before delivery
- ARVs not prescribed, not accepted, concerns about adverse effects
- ARV prophylaxis failures? (drug resistance, nonadherence or other causes)
- ongoing new HIV infection in women
- role of street drugs and alcohol, homelessness.

Looking more closely at available data (22 NYC pediatric HIV care sites) on the 5% of infants born to HIV-infected mothers in 1999 or 2000, no single obstacle can explain all of the infections.

Even with our best efforts, antiretroviral prophylaxis for perinatal HIV prevention might not be succeeding. Monica Nolan, an EIS officer with CDC's Division of HIV/AIDS Prevention, is examining apparent ZDV failures in children in the Pediatric Spectrum of Disease (PSD) study in NYC . We hope she will uncover data which can inform scientific monitoring of prenatal management to eliminate failures.

The diversity of the NYC populace contributes to obstacles in care and prevention. One third of NYC population is foreign-born and 49% of 1999 births were to immigrant mothers. Some immigrants are undocumented or lack health insurance. Differences in language and culture also make counseling and other communication very difficult.

Illicit drug use may also play a role in the ability of some women to obtain optimal care. Data from the Pediatric Spectrum of Disease study show how prevalent drug use is among HIV-positive mothers. Through 1988, injection drug use was common among drug-using mothers reported in PSD. After 1989, injection drug use began to decline, but mothers using other street drugs remained relatively constant. Among women who used any drugs, over a third had no prenatal care, compared with 7-12 percent of mothers with no history of drug use.

HIV seroprevalence by race and ethnicity show significant disparities, including among NYC women testing HIV-positive. NYS Department of Health data show a persistently higher percentage of Black and Hispanic women in NYC testing HIV-positive as compared with other racial and ethnic groups, although percentages in all groups have been declining over the last decade.

Risks for HIV in Women of Childbearing Age

The last data I will present underline the need for alliance between pediatric and adult HIV prevention. STD reports are one way to see evidence of unprotected sex. Since chlamydia became reportable in 1994, more than 20,000 cases have been reported in women each year in NYC. In 1999, 64% of these cases were in women 15- to 24-years of age, and only 31% in women older than 24.

Similarly, gonorrhea disproportionately affects young women. From 1993 through 1999, rates of gonorrhea in females aged 15-19 have generally been double the rates of males in that same age group and five times the rate of male and female gonorrhea in all age groups. In 1999, the rate for 15- to 19-year-old females in NYC was 799 reported cases per 100,000.

If we look at the percentage of HIV-positive women, by age group and year of delivery of their infants (for the period 1990–1999 in NYC), we note a decrease in all age groups, but this decrease is much less in women in the 15-19 and 20-24 year age groups. In addition, in a recent survey of young NYC men (ages 23–29) who have sex with men, the mean number of lifetime partners was 17, with some reporting up to 2000 lifetime partners; 16.9% tested positive for HIV(32.9% of Black men and 14.9% of Hispanic men). While self-identifying as MSM, many of these men reported also having sex with women.

Conclusion

Perinatal HIV has been reduced and can be eliminated in NYC. To do that we must:

- first prevent HIV infection in women;
- implement innovative approaches to prenatal care;
- ensure universal prenatal HIV testing; and
- provide access to excellent HIV care for women.

Steps to eliminate perinatal HIV in NYC that are underway or planned include:

- *Personal*:
  - better focused public education (NYC project)
- *Social*:
  - improve availability of prenatal care

        - adapt clinic schedule and policy to eliminate waiting, allow walk-ins? longer hours
        - outreach to women in high-risk neighborhoods (NYS program)
- *Structural*:
    - increase prenatal testing
        - provider education (NYS project)
        - universal prenatal HIV testing (legislation or regulations).

Substance Abuse, Pregnancy and HIV

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Although often approached separately, the two epidemics of drug abuse and addiction and of HIV/AIDS are now totally intertwined. The abuse of both legal and illegal drugs during pregnancy and the associated consequences of this abuse create a unique period of risk for the women affected. The transmission of HIV to the fetus by a woman infected with HIV as a result of her own drug use or through high-risk sexual behaviors has raised the level of concern, controversy and commitment for change. Therefore, pregnancy is also a unique time for prevention and intervention to attenuate adverse outcomes.

Substance Abuse in Women

The National Household Survey on Drug Abuse is the primary source of information on the prevalence and incidence of illicit drug, alcohol and tobacco use in the civilian population age 12 years and older. Results of the 1999 Survey which was conducted by the Substance Abuse and Mental Health Services Administration (SAMSHA) were made available in August 2000. Among pregnant women age 15-44 years, 3.4 % reported using illicit drugs in the month prior to the interview. Overall, the rate among non-pregnant women was significantly higher at 8.1%.

Young women merit specific attention. Among pregnant women age 15-17 years and 18-25 years, the age groups with generally higher levels of use, rates were 7.5% and 6.5%, respectively.

The 1999 National Household Survey on Drug Abuse also provided information on patterns of drug use. Among the 3.4% of pregnant women who reported any illicit drug use, marijuana (76%) was most commonly used. And, despite the burden of disease and risk associated with cocaine and heroin use, 8% of pregnant women reported use in the last month.

The non-medical use of prescription psychotherapeutic drugs has the third highest prevalence among women, regardless of pregnancy status. Among pregnant women the use is almost evenly divided between the categories of pain relievers, tranquilizers, stimulants and sedatives.

Pregnant women report lower use of pain relievers and tranquilizers than do non-pregnant women. However, the percentage of pregnant women reporting use of the stimulant methamphetamine in the past month is the same as that of non-pregnant counterparts.

With support from the National Institute of Drug Abuse (NIDA), the Community Epidemiology Work Group (CEWG) is a network of epidemiologists and researchers who review current and emerging trends in substance abuse. One of the sources for the CEWG database is ADAM, the Arrestee Drug Abuse Monitoring Program. According to ADAM, there are several major metropolitan areas where the percentage of female arrestees who test positive for cocaine exceeds that of men. The data source does not differentiate women who may have been pregnant.

Women who are crack cocaine users are at particularly high risk of acquiring HIV infection. The NIDA Cooperative Agreement for AIDS Community-Based Outreach/Intervention Research Program supported multiple sites to evaluate standard and enhanced interventions for HIV counseling and testing. The NIDA risk-behavior assessment (RBA) used in the study yielded descriptive information about a variety of substance abuse and HIV risk behaviors. In addition to cocaine injection behaviors, increased risk of HIV transmission among cocaine users is mediated through sexual behaviors. Women who use crack cocaine and who report exchanging sex for drugs were found to have more sexual partners, to have had sex more often, to use drugs before and during sex frequently and to have higher rates of STDs, including HIV infection. Women who exchanged sex for drugs were more likely to be African-American, homeless, or involved with the criminal justice system. Women who had previously been in substance abuse treatment were also more likely to be exchanging sex for drugs. These characteristics inform policy, program and research needs related to this very important risk factor for acquisition of HIV infection.

Men continue to constitute the majority of heterosexual, injection-related AIDS cases in sites surveyed by the CEWG. However, in the first half of the 2000 reporting year there were several survey areas where the proportion of female AIDS cases related to injecting drug use are significantly higher than the proportion of male cases.

Perinatally-acquired HIV infection is associated with a personal history of injection drug use or sex with an injection drug user in between 40-72% of cases. In addition to the increased risk behaviors associated with drug abuse, there is some evidence that there are other substance abuse factors that increase the risk of transmission of HIV from an infected mother to her fetus. Drugs of abuse might have a direct effect on the maternal-fetal interface, that is, the placenta. Cocaine causes vascular inflammation and, if the placenta is affected, the normal barrier between maternal and fetal circulation could be interrupted. The fetus itself may become more vulnerable to acquiring HIV infection if there is a direct or indirect effect on the developing immune system as a result of maternal infection. Persistent cigarette smoking during pregnancy has also been shown to be associated with an increased likelihood of perinatal transmission.

Consequences of Co-morbidity

Hepatitis C virus (HCV) infection accounts for approximately 20% of all cases of acute viral hepatitis in United States. Progression to chronic hepatitis occurs in 70% of affected persons. Hepatitis C is easily transmitted through exposure to blood and less readily through exposure to semen, saliva or urine. Intravenous drug users account for at least half of patients in most series. Among HIV-positive

individuals with an IDU history the infection rate for hepatitis C approaches 60%. The highest rates of new infections are among persons 20-39 years of age, which corresponds to peak reproductive ages in women. Co-infection with HIV modifies the natural history of chronic hepatitis C with a resulting rapid progression to cirrhosis. Alcohol use in the face of hepatitis C also decreases the time interval to serious liver damage and failure.

Jointly sponsored by the National Institute of Allergy and Infectious Diseases, the National Institute of Child Health and Human Development, and the National Institute on Drug Abuse, the Women and Infants Transmission Study (WITS) is an ongoing, prospective, multicenter study of the natural history of HIV-infected pregnant women and their infants. Pregnant women have been enrolled since 1989. Results of one review of WITS data reveal that perinatal transmission of HIV infection is approximately two times more frequent when mothers are also infected with HCV. Further study is needed to determine if the association represents an independent biologic effect of HCV infection or whether HCV is a marker for another cofactor such as continued drug use.

WITS also evaluated the risk of HCV vertical transmission in women with dual infection. HCV infection was detected in 8.4% of infants born to women who were infected with both HIV and HCV. This transmission rate is approximately two-fold that of the conservative estimates for HCV transmission from an infected mother to her infant.

There are complex dynamics related to immune system function and dysfunction that are hypothesized to account for these phenomenon. There are aspects of antiretroviral therapy that may actually result in an increase in HCV viral load and therefore increase the risk for transmission.

Substance abuse is associated directly and indirectly with a number of medical consequences as well as co-morbid conditions. Some of these conditions, such as tuberculosis and alcoholism, have consequences for public health as well as individual health. There are significant costs associated with all of these consequences. Substance abuse and addiction in women are associated with additional obstetrical and gynecological consequences: low birth weight, preterm labor and delivery, placental accidents, hypertensive disorders, chronic pelvic pain syndromes, and abnormal menstrual bleeding. Abuse of legally available substances, alcohol and tobacco, actually account for the greatest adverse perinatal consequences.

Underlying medical conditions such as depression or other mental health disorders may influence the initiation or continuation of substance abuse. Female drug users are more likely to suffer from depression and anxiety disorders than the general population or people with other medical conditions. The cognitive dysfunction and neurotoxicity associated with drug use may result in unrecognized disease exposures that increase the risk for HIV infection and other blood-borne infections. This same cognitive dysfunction, especially among individuals who are binging, decreases the recognition of, and attention to, other physical signs and symptoms.

Comprehensive Care Model

To be effective, treatment of substance abuse must address the individual's drug use and any associated medical, psychological, social, vocational and legal problems. This list of elements of services is somewhat overwhelming but can be more easily embraced if a process model is applied to it. Each one

of these activities or supporting services is part of a treatment process sequence that, when linked and interactive, will yield the more successful treatment outcomes over time. Ultimately, treatment of abuse and addiction can be as successful as treatment of other chronic conditions such as diabetes or hypertension.

Medical detoxification is a process whereby individuals are systematically withdrawn from addicting drugs in an inpatient or outpatient setting, typically under the care of a physician. Opiate detoxification is carried out in pregnancy under medical supervision and methadone maintenance is initiated, if necessary, to stabilize the woman medically and to improve functioning.

Other important pharmacological interventions include the treatment of co-morbid conditions common in drug using populations. Use of anti-depressants in drug users with associated mental illness are as important as therapies directed specifically to the effects of the drugs of abuse.

As reported at the 1997 National Institutes of Health Consensus Development Conference, "Interventions to Prevent HIV Risk Behaviors," studies have shown repeatedly that people using drugs are amenable to behavior change strategies, and behavioral interventions can be effective in reducing the spread of HIV. Motivational enhancement therapy is a client-centered counseling approach for initiating behavior change by helping individuals to resolve ambivalence about engaging in treatment and stopping drug use. This approach employs strategies to evoke rapid and internally motivated change in the client. Research needs to be expanded to evaluate the use of this type of intervention during pregnancy when immediate cessation of drug use and abstinence are desirable to prevent negative consequences for mother and fetus. Success with stopping drugs would allow a greater opportunity for voluntary counseling and recommendation for testing for HIV, other blood-borne infections and medical consequences, as well as for family and social assessments.

The relationship between posttraumatic stress disorder (PTSD) and substance abuse has been increasingly identified as a significant clinical and research focus. Women with current PTSD comprise 30-60% of substance abuse treatment samples and experience a more severe course than women with either disorder alone. Many affected women are polysubstance abusers with cocaine as a frequent drug. Many women have definite histories of significant childhood and early adult psychological, sexual and physical traumas. A superimposed pregnancy may have the potential to exacerbate symptoms particularly, where triggers are concerned and thereby limit adherence to recommended prenatal prescriptions and proscriptions.

Barriers to Care

In order to structure a comprehensive perinatal program for substance-abusing women, an understanding of the barriers to care is required. The three most relevant barriers are the attitudes and behavior of substance-abusing women, the attitudes and lack of understanding of the pregnant addict by obstetric care providers, and the lack of coordination between obstetric care providers and those professionals involved in mental health and drug abuse treatment.

Attitudes and concerns of substance-abusing women that may provide a barrier to care include:

- social alienation

- stigmatization
- fear of losing custody of children
- fear of prosecution
- acceptance of treatment under duress.

The results of a national survey of primary care physicians and psychiatrists to examine screening and intervention practices for illicit drug use were recently published (Friedmann PD, et al. *Archives of Internal Medicine* 2001 January 22;161(2):248-51). The investigators, partially supported by NIDA, reported that 32% of primary care physicians and psychiatrists indicated that they do not inquire routinely about illicit drug abuse. Psychiatrists and obstetrician-gynecologists were most likely to screen for drug abuse. However, obstetricians-gynecologists were least likely to intervene. Details of whether this behavior differed with pregnant versus non-pregnant patients are not known. Only 55% of physicians reported that they routinely recommend formal addiction treatment to drug-abusing patients and a substantial minority (15%) do not offer any intervention. Psychiatrists were most likely to intervene but were more likely to refer patients to a 12-step program. Optimism about the effectiveness of treatment was correlated with increased screening. Screening behavior also differed by the type of patients in the practice. If patients were older than 50 years of age, screening was less common, perhaps correlated with the correct perception of lower prevalence of illicit drug use among older people. Greater screening among physicians who treat more black patients is a little harder to explain. The actual prevalence of illicit drug use in the black population is 7.5% versus 6.4% among whites; this suggests that a potential bias exists among some physicians.

Other studies have demonstrated that stigmatizing attitudes on the part of physicians limits their self-efficacy in screening for substance abuse. A corollary is that similar bias exists in determining who should be offered counseling and recommended screening for HIV infection.

The final barrier to care is the lack of coordination of resources as a result of :

- separate service delivery systems
- separate funding/reimbursement mechanisms
- limited availability of interventions for non-opiate abuse/addiction, and
- limited relapse prevention services in postpartum period.

Challenges for Practice and Research

Behavioral therapy for adolescents incorporates the principle that unwanted behavior can be changed by clear demonstration of the desired behavior and consistent reward of incremental steps toward achieving it. Stimulus control, urge control and social control are the three elements of this type of therapy. The latter involves family members and other significant others in helping patients to avoid drugs. However, for pregnant adolescents, the pregnancy may be part of disengagement from the nuclear family or may result in being ostracized. The adolescent receives treatment as an emancipated minor and is expected to function as an adult. There is a need for more research on developmentally appropriate behavioral interventions for adolescents during pregnancy and for research related to other costly reproductive health behaviors.

Women who are actively using drugs when they become pregnant and who continue to use drugs may

not engage in prenatal care at all or until later stages. When they do access the system they encounter an approach to care that may not have the flexibility to adjust to their needs. On behalf of presumed fetal benefit, there is often a reluctance to be aggressive with pharmacotherapies such as methadone where a significantly increased dose may be needed to eliminate illicit drug use.

Effective therapy for substance abuse is typically at least one year in duration with relapse-prevention strategies often required. Even under the most optimal circumstances of early pregnancy identification and entry into prenatal care, the duration of involvement in the obstetrical care system is limited to the proverbial nine months. A continuum to after-care for both primary care and substance abuse care is often lacking. The treatment plan for a postpartum woman, particularly if HIV-infected or with an experience of an adverse pregnancy outcome, may require some adjustments to the content or intensity of the interventions in a continuing care plan. This is the difference between care to a substance abusing woman who had become pregnant as compared to a pregnant substance abuser.

At the same time that we have the greatest need for a network of services to be coordinated for an individual, there is a greater intensity and complexity to the specific elements of care once the cascade of morbidity is set in motion. Therefore, prevention of the transition from use to abuse to addiction and treatment of addiction is a primary goal for practice and research.

Perinatal HIV Surveillance: A Tool for Targeting and Evaluating Perinatal Prevention Programs

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This morning we will present an overview of perinatal HIV surveillance and then show several examples of how state and local health departments are using their surveillance data for planning, targeting and evaluating prevention programs.

Overview of Perinatal HIV Surveillance

HIV/AIDS surveillance is the major tool used by CDC and state and local health departments to track the epidemic. Surveillance activities provide demographic, laboratory, clinical, and behavioral risk data to identify populations at greatest risk for HIV infection and to estimate the size and scope of the epidemic at the national level.

The population groups important to perinatal surveillance include: HIV-infected women, HIV-positive pregnant women, HIV-exposed infants, HIV-infected infants, infants who develop AIDS, and those exposed and infected infants who die. CDC and the Council of State and Territorial Epidemiologists (CSTE) support surveillance of perinatal exposure and HIV infection as an extension of AIDS surveillance. The American Academy of Pediatrics issued a policy statement in 1998 in support of reporting HIV exposure and infection (*Pediatrics* 1998 Feb;101(2):315-9). Collecting surveillance data

on HIV-exposed and infected infants is critical to states' ability to target prevention and care resources and to the timely evaluation of perinatal prevention activities.

Reporting laws and regulations vary from state to state. Since the early 1980's, all state and local health departments have been conducting routine surveillance for perinatal AIDS. Currently, there are 36 areas that conduct named-based HIV infection reporting, and there are 9 areas that use coded identifiers for perinatal HIV reporting. Most of the states conducting HIV infection reporting also conduct surveillance on HIV-exposure in infants.

The overall objectives of perinatal surveillance activities include

- characterizing recent trends in the perinatal HIV and AIDS epidemic;
- assessing the implementation and impact of the Public Health Service perinatal prevention guidelines (HIV counseling and timely HIV diagnostic testing of the mother, the offering of antiretroviral therapy to HIV-positive women, avoidance of breast-feeding, and--for HIV infected infants--receipt of PCP prophylaxis);
- contributing relevant, scientifically-based data to assess the resource needs for prevention and for care;
- assessing prevention failures or missed prevention opportunities; and
- contributing data to help target and evaluate the effect of prevention efforts and activities.

In order to meet these surveillance objectives, a combination of both routine and enhanced surveillance methods are used:

- routine perinatal surveillance
  - population-based
  - active and passive case ascertainment
  - follow-up of exposed infants
- enhanced surveillance methodologies
  - enhanced case ascertainment
  - multiple sources of data
  - more complete and additional data
- collaboration with HIV prevention, MCH, other perinatal surveillance, and substance abuse programs.

In 1996, the routine perinatal surveillance system was expanded and enhanced methods were instituted in 7 states. These areas collected enhanced perinatal surveillance data for infants born in 1993 and in 1995-1997. Because of the completeness and quality of these data, they were instrumental in demonstrating the rapid implementation of the PHS guidelines and the success of voluntary testing for HIV in preventing perinatal infections. In late 1999, the enhanced surveillance methods were expanded to include 22 states and 4 cities most affected by the perinatal epidemic.

In all areas funded for enhanced surveillance and in many other states as well, perinatal surveillance staff have either begun or have increased collaborative efforts with HIV prevention, Maternal and Child Health, other perinatal surveillance (e.g.,Group B Strep, syphilis), and substance abuse programs.

Since 1995, data collected through routine surveillance have included mother's HIV status, the timing and number of prenatal care visits, receipt of antiretroviral therapy (prenatal, intrapartum, and neonatal), type of delivery (vaginal versus c-section), and the occurrence of birth defects. To supplement these data, enhanced perinatal HIV surveillance collects data on:

- more specific details of timing and receipt of prenatal care, birth history, and combination ART
- maternal and infant disease screening
- maternal reproductive history
- maternal drug use and STDs during pregnancy
- rapid testing at delivery
- antiretroviral resistance testing in infant
- assessment of maternal and infant care.

Project Sites

Twenty-six project areas in 22 states receive funding for enhanced surveillance: Alabama, California, Chicago, Connecticut, District of Columbia, Florida, Georgia, Houston, Los Angeles, Louisiana, Maryland, Massachusetts, Michigan, Mississippi, New Jersey, New York State, New York City, North Carolina, Ohio, Pennsylvania, Philadelphia, Puerto Rico, South Carolina, Tennessee, Texas, and Virginia. Some of these sites receive funding for both perinatal prevention and enhanced surveillance. The states of Illinois (outside of Chicago) and Delaware receive funding only for perinatal prevention.

For those areas that will be conducting enhanced surveillance using named HIV exposure and infection reporting, ascertainment of mother-infant pairs will be accomplished using:

- active case finding at pediatric sites and OB hospitals
- matching of HIV/AIDS registry to birth registry
- case reports of women pregnant at time of report to health department
- laboratory reporting – if not already being used as a routine part of case finding.

For those areas that do not currently have HIV exposure and infection reporting or will be conducting enhanced surveillance using unique coded identifier (versus a name), ascertainment of mother-infant pairs will be accomplished using facility based IRB-approved protocols. For example, names will remain at the facility and a study-assigned identification number will link the records at the facility to the record in the surveillance data base and will allow for linking of the mother and the HIV-exposed child. Data will be collected from both the mother's and the child's medical records. To try to ensure that the data are representative, facilities with the largest number of births to HIV-positive women will be selected.

Many of these project areas will also be collaborating with other programs (e.g., Pediatric Spectrum of Disease project, Medicaid) to identify mother/infant pairs and will be able to obtain data from mothers' and infants' medical charts. In addition, perinatal AIDS case reporting, which continues at all sites, will provide areas with a population-based approach to determining reasons for prevention failures. And over the next few years, those areas that do not have HIV exposure and infection reporting will be working toward implementation of reporting either by name or unique code.

All states that have been collecting both routine and enhanced surveillance data have also been looking at data to assess and evaluate prevention efforts aimed at each stage of the cascade of services. The state and local areas have been specifically looking at indicators to determine both prevention successes and missed opportunities. For example, they:

- assess the proportion of mothers of HIV-exposed children who received prenatal care;
- assess the proportion of these mothers who were:
  - counseled about HIV
  - offered and accepted HIV testing
  - offered and accepted ART;
- determine rates of c-section for HIV prevention and of abstinence from breast-feeding;
- assess prevention failures; and
- assess impact on perinatal transmission rates.

Examples of State/Local Uses of Perinatal Surveillance Data

New Jersey. New Jersey conducts HIV-exposure and infection reporting, by name, statewide. It was one of the original 7 states that implemented enhanced surveillance methodologies and has enhanced data beginning with the 1993 birth cohort. Comparing surveillance data to data from the state-based Survey of Childbearing Women (SCBW) demonstrates that from 1993-1998, surveillance data have been very complete (80%-90%). Surveillance data for 1999 are less complete at this time due to a delay in the birth registry match, which is an integral part of enhanced perinatal surveillance.

New Jersey has used SCBW and enhanced surveillance data to target prevention interventions to African American and Latino women residing in Newark, Jersey City, and Paterson. The data show that African American women of childbearing age have a rate of HIV infection 13 times greater and Latino women have a rate 8 times greater than that for white women. Additionally, surveillance staff have assisted their prevention staff in data base development, specifically for evaluation of outreach and referral activities and continual assistance in the guidance of local prevention programs.

New York City. Since 1988, the New York State Department of Health has tested all newborns for HIV. From 1988 through January 1997 this was done as a blinded serosurvey. Since February 1997 the testing has been conducted through the statewide mandatory newborn HIV testing program. Since 1989, pediatric HIV-exposure and infection surveillance in New York City has been facility-based, conducted at 22 sites using IRB-approved protocols. In June 2000, New York State implemented named HIV-infection reporting for adults and children.

Comparing serosurvey data to surveillance data demonstrates that completeness of surveillance reporting has improved over time and, in 1998, 74% of NYC births were identified and reported from the 22 pediatric sites that participated in Pediatric HIV Surveillance Projects (1999 surveillance data are incomplete at the time due to routine reporting delays).

Philadelphia. Philadelphia has conducted HIV-exposure and infection surveillance based on voluntary reporting by health care practitioners. Recently, however, Philadelphia passed a resolution requiring reporting of HIV-positive women and their HIV-exposed infants, by name, to the city health department.

Philadelphia uses surveillance data to describe the perinatal epidemic geographically. The distribution of female AIDS cases by zip code of residence at diagnosis and the distribution of voluntarily reported perinatal HIV-exposures are plotted onto a map. These data are very useful for prevention planning and could be used over time to help evaluate prevention programs, for example, social marketing campaigns targeted to particular zip code areas.

The University of Pennsylvania, Drexel University, and the Philadelphia Department of Health worked collaboratively on an analysis of surveillance data that was presented this month at the Retroviruses and Opportunistic Infections Conference in Chicago. They reported on 250 births to HIV-infected women in Philadelphia between 1994 and 1998. In a logistic regression model, receipt of inadequate prenatal care and black race were significantly associated with failure to receive prenatal antiretroviral therapy during pregnancy.

The authors then characterized mothers who did not receive prenatal care. Factors shown to be associated with lack of prenatal care for these HIV-infected pregnant women were: injecting drug use or unidentified risk for HIV, non-Hispanic ethnicity, smoking, and use of alcohol.

As the authors concluded, efforts to characterize barriers to obtaining adequate prenatal care and to understand racial disparities in receipt of prenatal antiretroviral therapy are crucial to prevention program planning.

Los Angeles. Because California does not have HIV infection reporting, enhanced perinatal surveillance in Los Angeles County is conducted using a facility-based approach with IRB-approved protocols. Project surveillance staff worked in collaboration with staff from the Pediatric Spectrum of Disease (PSD) project. Based on PSD data, the sites chosen for facility-based enhanced perinatal surveillance report about 97% of all prenatally-exposed cases. PSD data show there has been an increasing use of maternal ZDV and decreasing rates of perinatal HIV transmission from 1995 through 2000.

South Carolina. South Carolina conducts name-based HIV-exposure and infection reporting statewide. State-wide trends in cesarean-section deliveries for HIV-exposed infants were assessed. In South Carolina the trend towards an increasing proportion of c-section deliveries mirrors the nationwide trend. However, the proportion of deliveries by c-section is variable by state – with some states seeing no increasing trend. This same analysis can be done looking at specific hospitals within a state. This local level data can be used for data quality assurance measures and to document areas to target for further prevention efforts and/or to help evaluate previously implemented activities.

Michigan. Michigan has name-based HIV infection and exposure reporting and was another of the original 7 states to conduct enhanced perinatal surveillance (birth years 1993-1998). Enhanced perinatal surveillance data have enabled Michigan health department staff to document progress toward the elimination of perinatal HIV in Michigan (*MMWR* article in press):

- trends in maternal and neonatal ZDV (1993-1998)
  - significant increases in maternal and neonatal ZDV use
  - very few women refused ZDV
- missed prevention opportunities
  - all HIV-positive infants had some contact with health care system

- factors associated with no or inadequate prenatal care
  - illegal drug and alcohol use more frequent in women with the fewest prenatal care visits
- compliance with Michigan counseling and testing laws
  - requires HIV counseling and testing of pregnant women unless the women does not consent to testing
  - high proportion of practitioners comply, but some missed opportunities for counseling, testing, and prevention therapy.

New York City. The Pediatric Unit of the Office of AIDS Surveillance in New York City publishes a semi-annual report which focuses exclusively on the perinatal epidemic in NYC. The report includes data on perinatally exposed and HIV-infected children. The report highlights data from HIV-exposure, HIV-infection, and AIDS surveillance, the Pediatric Spectrum of Disease Project, vital statistics on HIV/AIDS related mortality, and the NYS Newborn Testing Program. The report is available on the internet at www.ci.nyc.ny.us/html/doh.

These are just some examples of how surveillance data are being used and disseminated. Perinatal surveillance data are also being used by Community Planning Groups and have been incorporated into many states' Epi Profiles, HIV/AIDS Surveillance Reports, HIV/AIDS slide sets and web sites, and many other types of publications used by local prevention planning groups.

Conclusion

In conclusion, surveillance data can be used for targeting prevention efforts to specific populations for maximal reduction in perinatal prevention. Surveillance data need to be able to identify women at risk for HIV infection, HIV-positive women at risk for becoming pregnant, HIV-positive pregnant women who need prenatal care and other medical and social services, and HIV-exposed infants. Specific prevention interventions can be targeted towards each of these populations.

Collaboration between prevention, surveillance, and other programs targeting women and children results in the best use of limited resources, avoids duplication of efforts, allows for coordinated services to women, and points to more opportunities to encourage women to know their HIV status--ideally before pregnancy but, if not, then early in pregnancy.

Many areas have established perinatal prevention working groups or task forces consisting of staff from prevention, surveillance, health services, STD, and Title IV programs within the health departments. Also included may be staff from HIV/AIDS education and training units, local community-based organizations, as well as local care providers.

The surveillance data being collected should be pertinent to HIV prevention efforts, address prevention program needs, be responsive to changing needs, and should be disseminated in a timely way to all those involved in planning, targeting, and evaluating prevention efforts.

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Evaluating Targeted Programs to Maximally Reduce the Transmission of Perinatal HIV

Stephanie Sansom
Division of HIV/AIDS Prevention–Surveillance and Epidemiology
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Evaluation of the targeted programs to reduce the transmission of perinatal HIV will involve a collaboration between staff from the epidemiology, program and surveillance branches at the Division of HIV and AIDS Prevention at the CDC, and staff from the 16 sites who have received funding from Congress. In this presentation, I'll be describing the roles of the prevention sites and of the CDC in the evaluation, the types of prevention programs, key measures of interest for the evaluations, data to assess program impact, and types of evaluation analyses.

We anticipate that each site will evaluate the impact of its own programs. CDC will provide technical assistance for program evaluations, and CDC will ask the sites to share data from their evaluations to assess how well various types of programs work across sites.

The sites are engaged in a variety of targeted programs to reduce perinatal HIV transmission. We've divided those programs into two main categories, according to the types of data that could be used to evaluate those categories. We call the first category of programs "individual-based," because these programs can be evaluated using the individual woman as the unit of analysis. Examples include rapid testing programs and case management programs. The second category of programs (e.g., community outreach, social marketing, or provider training programs) is called "population-based" because we'll most likely be relying on population-based data to determine their effectiveness.

Types of Measures

Process, impact and outcome measures are the types of measures that we'll be working with the sites to collect. Process measures indicate how well a program is being implemented. Impact measures show how well a program is reaching its intermediate goals – these measures are likely to address various steps along the cascade of events that lead to perinatal transmission. The outcome measure indicates how well the program is reaching its primary objective, in this case, reduced perinatal HIV transmission.

Some brief examples of process measures include:

- the proportion of women eligible for rapid testing who are, in fact, offered rapid testing;
- the number and type of services provided to case management clients; and
- the number of providers who attend training sessions on, for example, voluntary HIV counseling and testing of pregnant women.

Examples of impact, or intermediate measures, include:

- the number of eligible women who accept a rapid test at labor and delivery;
- the change in the proportion of:

- HIV-positive case management clients who get appropriate preventive treatment during their pregnancy;
- providers who offer counseling and testing to all pregnant women.

Of course, the key outcome measure is the change in the proportion of HIV-positive women who transmit the infection to their infants.

Different types of programs address different steps along the cascade that lead to perinatal transmission of HIV. Social marketing and outreach programs are most likely to target the first steps of the cascade, that is, prenatal care and counseling and testing of pregnant women. To the extent that case management is focused on pregnant women already known to be HIV-positive, case management should help ensure that these women get appropriate treatment and that transmission of HIV to their infants is prevented. Rapid testing potentially addresses a broader range of the cascade – testing pregnant women at labor and delivery and, if they are positive, providing them with treatment that will ultimately prevent transmission. Similarly, provider training, depending on the focus of the training, could impact many steps of the cascade, from counseling and testing pregnant women to appropriate treatment of HIV-positive pregnant women.

In its assessment of program impact across sites, CDC will be particularly interested in three key measures. The first, of course, is the outcome measure, that is, the change in the proportion of HIV-positive women who transmit HIV to their infants. Two of the intermediate impact measures also will be looked at closely: 1) the proportion of pregnant women who receive voluntary HIV counseling and testing during pregnancy; and 2) the proportion of HIV-positive pregnant women who receive appropriate preventive treatment.

Data Collection

A chief challenge for the evaluators will be obtaining data on the measures of interest and, in particular, identifying data to measure changes in testing rates among all pregnant women. The states have many different mechanisms for collecting these data. Some states record HIV counseling and testing information on their birth certificates. Others note it on newborn screening forms. A few states use the PRAMS survey of women who have recently delivered to determine testing rates. Medicaid is a potential source of testing data. A few states are engaged in audits of medical records to learn about various types of testing that occur during pregnancy.

Collection of data on the other two measures of particular interest to CDC – the proportion of HIV-positive pregnant women who get appropriate preventive treatment, and the proportion of HIV-positive women who transmit HIV to their infants – may be more straightforward. For the majority of sites that are conducting enhanced perinatal surveillance, these data will be available from the enhanced perinatal surveillance forms. CDC will be working with sites that are not conducting enhanced perinatal surveillance to utilize other mechanisms available for collecting data on these measures.

We also will want to collect additional data to help evaluate program success. For instance, in any given targeted area, there may well be other HIV prevention programs in operation. We'll want to document the existence and purpose of those programs and try to understand the impact those programs may have had on our measures of interest. CDC will want to help the sites look at program costs. Finally, there

may be room for a qualitative component to this evaluation, especially because our task is to reach a small population of difficult-to-access women. Case studies – without identifying individual women – of how to reach and provide services to this population may turn out to be a very useful component of the evaluation.

Data Analysis

To evaluate the individual-based programs, it will be important to assess whether the targeted services provided to individual women were related to improvements in rates of testing, treatment and transmission. Most of the programs centered around rapid testing will collect impact data on uninfected women, particularly on the proportion of eligible women who were tested by the time of delivery. Outcomes for HIV-positive women who were determined to be positive through rapid testing, or who were enrolled in case management because they were pregnant and HIV-positive, will be linked to programmatic activities, or the services provided to these women. The goal at the local and CDC levels will be to approach the evaluation of targeted programs as a collaborative effort between epidemiology, program, and surveillance staffs.

For the population-based programs, such as social marketing, community outreach and provider training, we expect that each sites' epidemiology, program and surveillance teams will collect population-based measures of testing, treatment and transmission before, during and after interventions. Having these data will enable us to evaluate program success using a time-series technique. In a time-series analysis, we look at rates (of a desired behavior or event such as testing for HIV) in the targeted population during a baseline period before the campaign begins, during the campaign and after the campaign ends. If rates increase after the campaign begins and remain higher than baseline rates in the period after the campaign ends, we would have some evidence that the campaign was associated with higher rates.

Another analytic technique that could be used along with time-series to demonstrate a program's impact is that of comparison groups. In this technique, evaluators would compare rates of a desired behavior or event in populations not targeted by a campaign to rates) in targeted populations during the same time periods (i.e, pre-, during, and post-campaign). Higher rates in targeted populations during and after the campaign and constant rates in untargeted populations would suggest campaign success.

To enable sites to share information about their programs and their evaluations, we are creating a web site for the prevention grantees. It will be a password protected website that only the grantees and the CDC will be able to access. We'll be asking you to submit information about your program activities and evaluation plans – some of you already have done this – to post on the web. We'd also like to post any instruments or materials you've developed that you're willing to share.

To conclude, the CDC will be offering technical assistance in the local site evaluations of the targeted programs and also will be collecting data to assess program impact across 16 funded program sites. For purposes of the evaluation, the programs fall into two types – those where the unit of analysis is the individual and those where the unit of analysis is a population. Data for assessing program impact will come from several sources including, where available, enhanced perinatal surveillance. A major challenge in some sites will be accessing data to measure testing rates among pregnant women. We'll encourage the use of both time-series analyses and comparison groups to evaluate program impact, and we'll also encourage more qualitative or descriptive analyses. We envision a strong partnership between

epidemiology, program and prevention staffs at both the local and CDC levels.

WORKSHOPS

Workshop 1: Social Marketing Campaigns: Challenges in Implementation and Evaluation

Moderators: Ken Dominguez and Angel Luis Ortiz Ricard

Mass Media Campaign to Promote Syphilis and HIV Testing in Pregnant Women (Puerto Rico, March--September 2000)

Rolando Jimenez, Pediatric AIDS Section, Puerto Rico Department of Health
Clemente Diaz, Department of Pediatrics, University of Puerto Rico School of Medicine, Children's Hospital

The rationale behind this campaign was:

- To develop a culturally sensitive and appropriate mass media campaign that addresses the issue of preventing perinatal transmission of HIV and congenital syphilis through the promotion of testing for syphilis and HIV among pregnant women
- To create awareness among pregnant women about the importance of being tested.
- Women are unaware or in denial about their own risk of getting infected and, more important, about the risk to which they expose their yet to be born child.
- Not all providers are offering HIV testing to their pregnant patients or fail to communicate effectively the importance of being tested.
- Pregnant women who did not consent to be tested perceived that their providers thought it was not important.
- Every woman with a positive result for any of these tests is informed about treatment options that reduce the possibilities of transmitting the disease to their babies. *This ensures access to appropriate prevention interventions to reduce the risk of perinatal HIV transmission and congenital syphilis*.
- There are still groups of women and infants who do not benefit from antiretroviral therapy.
- This campaign represents another strategy that supplements the ones currently being used to reduce perinatal transmission of HIV.

One goal of the Puerto Rico Department of Health is to reduce the rate of perinatally acquired HIV infection and congenital syphilis in Puerto Rico by the year 2003. Strategies that have been used to reduce perinatal transmission include:

- Official, written, public policy guidelines were developed to promote voluntary HIV testing among pregnant women.
- Resources were made available to help providers comply with the guidelines.
- Educational materials were developed and supplied to providers and clients.
- Training for health and non-health care professionals was offered.
- Mass media campaign was designed, joining experts in marketing and communications with DOH staff.
- Site visits were scheduled to all health care regions in Puerto Rico.

The objectives of the mass media campaign were: a) to create awareness of services, treatment guidelines and prevention strategies; and b) to educate pregnant women about their right to ask their medical care providers to make available to them the syphilis and HIV tests during their prenatal care.

The Department of Health's Pediatric AIDS Program worked with its programs for the prevention of HIV and other STD and with a marketing company to come up with an action plan for the campaign. During the period March--September 2000, five radio stations carried 728 re-transmissions of the prevention message. Four local televison channels aired 344 messages in prime time. There were an estimated 303 repetitions of these messages on cable television. Thirteen ads ran in five local newspapers and 2,500 posters were distributed. The posters contained one of two messages:

- "Igual de Absurdo" ("The Same Nonsense")
- "Tu diagnóstico" ("Your Diagnosis").

Finally, 60 movie theaters carried the "Igual de Absurdo" and "Tu diagnóstico" messages. This insured island-wide coverage.

To enhance the impact of the campaign, prevention messages were culturally sensitive and appropriate to the audience. In addition, posters were placed in settings highly frequented by pregnant women (health clinics, medical offices, hospitals, etc.).

Evaluation

Focus group methodology was utilized to determine the appropriateness of the HIV and syphilis perinatal prevention media campaign. Sixteen focus groups (8 groups of female adolescents 18 years of age or younger and 8 groups of female adults 19 or older) were convened. Convenience sampling (non-random) methodology was used to determine the composition of each group. A moderator explained the purpose of the focus group to participants. Demographic information on the participants was obtained via a questionnaire. Perceptions, opinions, and knowledge of the participants was also assessed by questionnaire. An annotator took notes during the discussion, which was recorded with written consent of the participants. Data analysis is in progress.

Preliminary findings from the focus groups (42 total participants) held in the high-incidence regions of Bayamon and Caguas indicated that the two age groups were about evenly represented; about 60% were from urban areas. A little over half were Catholic, about one-sixth were Protestant, and the remaining had "other" or "no" religious affiliation. Fifty-six percent indicated education below the 12th grade; the others were evenly divided between a 12th-grade education and 4 years or more of college.

Qualitative findings of these focus groups in the regions of Bayamon and Caguas are available. In response to general questions:

- They liked the advertisements used in the campaign because they promoted HIV testing.
- They felt the ads should have appeared more frequently.
- They showed preference for the TV commercials and posters over the radio ads. Women thought they explained better the perinatal prevention message.

- They would have changed one of the posters by taking the baby off the street.
- The advertisement campaign told them that it is important to be tested for HIV and syphilis.

In the area of perceptions and opinions, participants:

- said that TV, radio and posters were adequate media to promote the syphilis and HIV perinatal prevention messages; and
- perceived sex, unprotected intercourse, and multiple sex partners as risk behaviors for HIV and syphilis.

In terms of knowledge, participants judged television as the most effective medium. Knowledge of HIV transmission was adequate but not adequate for syphilis transmission. We can conclude that a media campaign to promote the prevention of syphilis and HIV perinatal transmission is one of several strategies to achieve reduction in transmission rates.

Red Ribbon Question Mark HIV Testing Campaign (Developed for the Maryland AIDS Administration)

Jim Williams, Center for Communications, Johns Hopkins School of Public Health

Maryland has recorded more than 20,000 AIDS cases since October 1981 and more than 23,000 Marylanders are currently living with HIV or AIDS. The rate of new cases remains high. The city of Baltimore has been particularly hard hit, with 10,672 cumulative AIDS cases (7th among cities in the U.S.). As many as 18,000 Baltimore city residents may currently be infected with HIV.

Three zip code areas in the city have been identified as having a particularly high prevalence of HIV and AIDS. Thus a social marketing campaign could be targeted to areas where demographic characteristics of the infected population could be determined and where it would potentially have the greatest impact.

The primary objective of our social marketing campaign was to increase the incidence of HIV testing in the City of Baltimore by 10% over the 6-month period of the campaign (December 1999–May 2000). Our primary audiences were: a) current or soon-to-be-pregnant women ages 12-34 living in the city of Baltimore; and b) men (and women) ages 12-34 who engage in risky behaviors in our zip code-targeted area, especially IDUs and MSMs and their partners.

Our campaign strategies were to:

- generate general awareness and urgency among the primary audience for HIV testing through the mass media (posters on the transit system, radio, TV);
- unite other HIV testing communication programs with a common logo and urge to action;
- use direct mail and premium items to remind prenatal caregivers to encourage HIV testing; and
- support local testing sites' communication and outreach programs with individualized promotional materials (banners, balloons, flyers, etc.).

The key issue for our first target audience, pregnant women ages 12-34, was a lack of knowledge as to why HIV testing is important. Our key message was that perinatal transmissions can be significantly reduced with proper treatment. The key media were posters on the transit system, radio, TV, and brochures; collateral items included calendars, shopping bags, coupons, brochures, and bumper stickers.

The key issue for our second target audience, prenatal caregivers, was missed opportunities to suggest HIV testing. Our key message was: "Don't forget to discuss HIV testing with EVERY pregnant woman." Key media were direct mail and CME training sessions. Collateral items included lapel pins, calendars, mouse pads, coffee mugs, post-it cube pads, and pens.

Negativity, fear, and skepticism about HIV testing were the key issues for our final intended audience, at-risk individuals (especially those in our targeted zip codes). Our key message was: "Be positive. End the anxiety. Find out about your status. You can live a long, healthy life with early detection and treatment." Key media were posters on the transit system, radio, and TV. Collateral activities included individual testing site promotions, incentives, outreach activities, and so forth.

The campaign was launched on World AIDS Day, December 1, 1999 at a popular mall. The event was hosted by a local radio personality and included entertainment by a group well-known to the target audiences. Aproximately150-200 attended; this included service providers, administrators and staff.

Evaluation

To evaluate the campaign, we used HIV testing data, random telephone surveys of the general public, a mall intercept survey of potential clients, surveys of providers, monthly activity reports from the telephone hotline, and anecdotal evidence. Briefly, the impact of the campaign was substantial.

Awareness of the advertising associated with the campaign was estimated at 76% market-wide, 92% in our three targeted zip codes. Those expressing an intent to get tested increased 19 percentage points as result of the campaign, to 46% of those surveyed. Calls to the telephone referral hotline were up 1500% (62% of callers cited the campaign as the impetus for the call). Over 80% of providers felt the campaign was "causing people to think about testing for HIV."
The campaign itself received several prestigious awards.

Various data sources indicate that HIV testing is actually up: an increase of 9.4% across multiple testing sites in the state (mostly in the city of Baltimore; an increase of 6.6% among residents living in the targeted zip code areas; and increases of 48% and 30%, respectively, at two health centers within these areas).

Discussion Summary

A question-and-answer session followed the presentations. Several key issues were raised, which are summarized below.

- Representatives from both campaigns emphasized the importance of involving the target audience

through outreach efforts and gaining their input in order to devise an effective social marketing initiative.

- Social and political environments can have a significant effect on a social marketing campaign, as evidenced by the Puerto Rican experience. Due to radical transformations in the public health structure of Puerto Rico, alterations to campaign messages and target audiences were necessary to maintain campaign effectiveness.
- In order to effectively target their audiences, television and radio spots for both campaigns were aired during prime time. This seemed to require some real negotiating. Those who launch HIV social marketing campaigns may be forced to deal with union politics, as was the case for Maryland.
- To provoke high response rates from providers, the Maryland campaign conducted repeated mailings of provider surveys and included office staff in their target efforts through the provision of promotional materials, such as mouse pads and calendars.
- The topic of campaign sharing was discussed. There are certain legalities involved around copyright issues, but the sharing of social marketing campaigns provides a cost-effective method to convey one's message. A campaign currently being launched in Georgia purchased the Baltimore ad that targets mothers for HIV testing. For questions regarding campaign sharing legalities and related issues, contact Dagmeris Richardson, Division Chief of Health Communications, Maryland State Health Department.
- The Puerto Rican, Maryland, and Georgia campaigns are using hotlines to measure campaign impact and to respond to public inquiries that are raised by the airing of television, print, and radio ads. In Maryland this proved to be an especially effective technique for measuring responses to radio ads (i.e., as measured by the amount of hotline calls received) immediately after the airings occurred.
- Two other HIV campaigns were brought up during discussion, that are currently being launched, or in the process of being launched, in Georgia and Massachusetts. The Georgia campaign actually purchased one of Baltimore's ads and is implementing altered versions. A previously existing hotline (Healthy Mothers, Healthy Babies hotline) is being utilized to address related responses and inquiries from those who are inspired by the ad and to measure the ad's effectiveness. In Massachusetts, a pre-campaign initiative was implemented from 1997-1999. This provided baseline measurements for the actual CDC-funded campaign which was launched in 1999.

After the question and answer session, Dr. Dominguez led the group in a review of important social marketing concepts and the development of a group consensus.

- The group decided upon the following definition for social marketing: "the application of commercial marketing techniques for social good." Stages of social marketing include market research, audience segmentation, the identification of consumer beliefs, and campaign monitoring and evaluation once the campaign has been initiated.
- The 5 P's are used to describe social marketing dynamics. They are: product, place, price (which includes non-monetary costs, such as embarrassment, inconvenience, or social stigma), people, and promotion. Dr. Williams includes "purpose" in his list of P's to emphasize the difference in primary purpose between social and commercial marketing campaigns.
- Social marketing references were provided: Phil Kotler's (1971) social marketing text and Alan R. Andreasen's *Marketing Social Change: Changing Behavior to Promote Health, Social Development, and the Environment* (1995). A useful website for social marketing references and information is located at http://www.social-marketing.com/
- Social marketing campaigns can be carried out through several channels, including television, radio,

print advertisements, promotional giveaways or events, and the enlistment or voluntary support of an advocate who is in the public eye (e.g., the cardinal in Puerto Rico, radio DJ in Maryland).

- To conduct an effective social marketing campaign, the needs and/or responses of target audiences must be measured and addressed before, during, and after campaign implementation. Hotlines and focus groups are effective tools for achieving these goals.
  - When using hotlines in conjunction with a campaign, it is important to staff them with well-trained interviewers who may successfully respond to callers' questions and educational or support needs. Workshop group members agreed that it is appropriate to collect personal information via hotlines, including race/ethnicity, gender, age, and zip code information, to enable the effective targeting of one's audience.
  - Focus groups, when effectively conducted, provide qualitative information from one's target audience(s), which can help to tailor the campaign to suit audience characteristics. Focus groups should measure a campaign's ability to reach its intended audience, as well as the acceptability of an ad among this audience (or among individuals who are representative of the target audience(s)). For Puerto Rico, focus groups were helpful in identifying an ad layout (i.e., the ad which depicted a child crawling amidst a busy roadway) that may have been offensive to the target audience, and hence ineffective, if it had been launched.

Workshop 2: Post-IOM Voluntary Counseling and Testing Guidelines and Re-authorization of the Ryan White Care Act

Moderator: Eva Margolies-Seiler

RWCA Re-authorization

Kristin Braun of the AIDS Alliance for Children, Youth & Families and Laura Hanen of the National Alliance of State and Territorial AIDS Directors described the provisions of the Ryan White Care Act Amendments of 2000 and subsequent responses and developments. The re-authorization included provisions for counseling and testing of pregnant women and added treatment services for these women.

Of the $4 million in new funds appropriated, $2 million is reserved for a) states with laws or regulations requiring testing of newborns, and b) two additional states demonstrating the greatest reduction in incidence of perinatal HIV (as determined by CDC). The other $2 million is to be distributed among states falling into the seven criteria outlined in the legislation, very likely to be the existing grantees. This $4 million was appropriated for this fiscal year only.

The Act also requests the Institute of Medicine (IOM) to conduct an evaluation of current perinatal prevention efforts and results to: a) determine the number of infants with HIV born to mothers of unknown HIV status; b) determine the barriers to testing of pregnant women; and c) make recommendations to states on how perinatal transmission can be further reduced. DHHS is to report to Congress on the progress made by the states. Under provisions of the ACT, IOM was given the option of declining this task. They have done so and the Inspector General's office of DHHS will do the

evaluation instead.

Two states (Indiana and Kentucky) are currently considering mandatory testing laws.

The proposed new Public Health Service (PHS) recommendations for HIV screening of pregnant women simplify the counseling and consent process for pregnant women. However, some state laws impose stricter requirements on providers than the PHS recommendations.

It is expected that there will be continued Congressional interest in perinatal HIV prevention.

New York State

Roberta Glaros of the New York State Department of Health's AIDS Institute discussed the legislative history of HIV testing of newborns in New York from the early 1980's to 1999. Current program requirements (established in 1999) include mandatory counseling of women in prenatal care and voluntary expedited testing of women presenting for delivery whose HIV status is unknown. If the mother does not consent to testing, her newborn is tested without consent immediately after birth. Expedited testing in labor and delivery setting allows for the administration of partial antiretroviral regimens to reduce perinatal transmission. Since these requirements were put in place, they have seen an increase in testing of pregnant women in the prenatal care setting. Now, ninety percent of pregnant women have been tested prior to their entrance to the hospital. An additional eight percent receive expedited testing in the labor and delivery setting. The remaining two percent are tested through the Department of Health's Newborn Screening Program.

A study of 631 HIV-positive women delivering in New York State from October 1, 1999 to June 30, 2000 demonstrates the effectiveness of the expedited testing policy. The study found that 72 HIV-positive women presenting for delivery (11 percent) had no history of HIV testing and did not know their HIV status. Expedited testing in the labor and delivery setting was completed on 54 of the these women, allowing for the administrative of partial antiretroviral regimens.

California

Toni Frederick presented. Since 1995, recommendations in Los Angeles County have been that all prenatal patients receive voluntary HIV counseling and testing. It has been mandated by law since 1996.

Data from the Pediatric Spectrum of Disease study from 1995-2000 were analyzed to determine why failures in prevention of perinatal HIV still occurred. Of 608 children born to HIV-infected mothers in the study, 10% were infected with HIV. Twenty percent of the mothers received no prenatal care; 13% were injection drug users. All three antiretroviral interventions (prenatal ZDV, ZDV during labor and delivery and neonatal ZDV) were administered to 67% of the mother-infant pairs. Seventy-four percent of the mothers received ZDV during pregnancy and 86% of infants received neonatal ZDV. As use of maternal ZDV increased over the period, rates of perinatal transmission declined. Prenatal care was highly correlated with intervention with ZDV.

Of the 11 HIV-infected infants born between 1998 and 2000 who received care in Los Angeles County, 6 of the mothers received prenatal care. Two of the infected infants were born to women who received ZDV prenatally and at labor and delivery; these cases represent treatment failure.

To evaluate whether prenatal HIV counseling and testing were being universally offered in the county, the Los Angeles County Department of Health Services interviewed pregnant women after prenatal visits at public and private clinics in the county between June 2000 and January 2001.

Of those surveyed, 95% had received information about HIV and pregnancy, about one-half had received information about HIV treatment and pregnancy, and 99% had been offered an HIV test. A total of 92% accepted the test; the main reasons for refusal were that the woman had already been tested or was in a monogamous relationship. Younger women (13-19 years) were less likely to accept HIV testing than women 20 years of age or older, although the difference was not statistically significant. Foreign-born women were less likely to accept HIV testing than U.S.-born women, but again, statistical significance was not reached. The results confirmed that, to ensure high test-acceptance rates, HIV information and counseling must be an integral component of prenatal care.

On the basis of this survey and other surveys done in Los Angeles County, the following gaps in prevention of perinatal transmission were identified. For those women with prenatal care, 5%-15% were not offered testing; 8%-20% did not accept testing; others were not retested later in pregnancy; and some delivered at a different hospital (i.e., not the HIV referral hospital) where there was either no hospital policy to ask about an HIV test or AZT was unavailable. For those women with no prenatal care (7%-20% among the HIV-infected), the problem is that rapid testing of HIV infection is currently not done.

If implemented as expected, non-named (unique identifier) reporting in California will pose several challenges: a) duplication of reports within a health department (lab reports and clinician reports); b) duplication of records within the state and outside the state (patient moving, multiple sources of care); c) educating providers (monitoring of their performance, accuracy of reports); d) problems with the unique identifier itself (changing last names, errors in dates, using “0000" for social security number); e) coordination with the PSD study (creating the unique identifier, clarifying reporting roles); f) matching babies and moms (coordination with enhanced perinatal surveillance); and g) how to address exposed babies (assign unique identifier or hold in the PSD database until infection status is determined).

Connecticut

Brian Forsyth from the Yale University School of Medicine commented on the effects of the Connecticut law that provides for mandatory HIV testing of all pregnant women. The law stipulates routine testing at the beginning of pregnancy and again at 26-28 weeks. If prenatal testing is not done, it is to be offered during labor and to the newborn. The law has been effective in increasing testing in pregnant women fourfold.

He compared the percentage of women tested in the pre-law period and 3 months and 9 months after the effective date of the law. There was an increase from 20% to 86% to 95%. Nine months after implementation of the law, testing in higher risk women increased from 40% to 70% to 80%. Perinatal

testing in the post-law period for women who did not have a prenatal test was administered to 62% of high-risk women and 27% of women not at high risk. Now, just 8.8% of women identified with higher risk remain untested prior to delivery. It would appear that the requirement for hospitals to offer perinatal testing to women of unknown HIV-status at time of delivery has driven the large increase in prenatal testing. One remaining barrier is the lack of a rapid test in some smaller hospitals since the "expedited" ELISA test is difficult for these hospitals to arrange.

Workshop 3:Prevention for Women without Prenatal Care (Rapid HIV Testing)

Moderator: Marc Bulterys

Perinatal HIV Rapid Testing: Medical Center of Louisiana

Robert T. Maupin, Jr., Maternal-Fetal Medicine Division, LSU Health Sciences Center
Denise Foxworth, Obstetrics and Gynecology, LSU Health Sciences Center

Denise Foxworth presented.

Perinatal HIV transmission rates in Louisiana have declined from around 25% in 1993 to about 5% in 1998 (latest published data). ZDV use in HIV-positive women giving birth in Louisiana increased from around 50% in 1993 to nearly 90% in 1999.

Administrative Region 1 of the State Department of Health and Hospitals includes the city of New Orleans. In this region, ZDV use in HIV-positive women giving birth increased from below 50% in 1993 to a high of more than 90% in 1998, but then decreased to near 80% in 1999. This decrease was accompanied by an increase in the number of babies born to HIV-infected mothers.

There are two HIV screening programs at the Medical Center of Louisiana at New Orleans. An ambulatory obstetric clinic screening program has an acceptance-of-testing rate of more than 99%. A total of 2,864 voluntary HIV screening tests revealed a seroprevalence in this population of 1.7%. Screening is also a part of inpatient obstetric services , which manage 3500-4000 deliveries annually; 10%-15% of women who present for delivery have had no prenatal care.

The Single Use Diagnostic System for HIV-1 (SUDS, Murex Corporation) is the only test approved by the Food and Drug Administration (FDA) for use in the United States. Our initial experience with SUDS testing revealed the following:

- 20% of HIV-exposed births were identified with SUDS tests in the first 7 months of screening
- 63% of SUDS+ women diagnosed during labor received intrapartum ZDV
- seroprevalence among women delivering with inadequate prenatal care was 4.8%
- SUDS positive predictive value was 100% when testing intrapartum women with inadequate

care.

In 1999, 703 women were screened with the SUDS test. Sixteen of 22 positive SUDS tests were confirmed by EIA and Western Blot. HIV seroprevalence was 2.3% among SUDS-tested pregnant women. Sensitivity/specificity of the test was 100% / 99.1%. Positive predictive value was 73%; negative predictive value was 100%.

In 2000, 1075 SUDS tests were performed. Ten of 16 positive SUDS tests were confirmed by EIA and Western Blot. HIV seroprevalence was 0.9% among SUDS-tested pregnant women. Sensitivity/specificity of the test was 100% /99.4%. Positive predictive value was 62.5%; negative predictive value was 100%.

In 1999, the monthly total of SUDS tests administered ranged from lows of 27 and 28 in February and October to a high of 151 in December, nearly twice as many as the previous high months of August (79) and September (78). In 2000, the monthly high was 133 in January. Number of tests remained fairly high through August when 123 tests were administered, then showed a steady decline to a low of 33 tests in December. Monthly totals of positive SUDS tests did not vary much (0–3) over the 2-year period.

A 6-month period (February–July) was reviewed to determine time to test completion. Median time for this 6-month period ranged from 79 to 105 minutes. During this same period the percentage of tests completed in less than one hour ranged from 24.1% to 39.7%; the percentage completed in less than 2 hours ranged from 70.3% to 83.6%.

To summarize our experience:

- SUDS tests demonstrate an adequate positive predictive value when employed in high seroprevalence obstetric settings.
- The efficacy of obstetric rapid testing appears greatest when applied to intrapartum patients with inadequate prenatal care in high seroprevalence populations.
- When appropriate rapid assays are available, the development of point-of-care testing will reduce delays in test reporting.

The Connecticut Experience

Susan Barringer, School of Nursing, Yale University School of Medicine

We decided to examine the use of two different methods of HIV testing in the perinatal period for women who have not been tested earlier in pregnancy: “expedited” ELISA and SUDS. Initiation of AZT therapy even within the first 48 hours of life may decrease the rate of transmission. Cesarean section can further reduce the risk of transmission.

SUDS is the only FDA-approved rapid HIV test. It has a false positive rate of about 1% (similar to ELISA). To make effective use of SUDS, a laboratory technician was on call 16 hours a day. Results were phoned to the clinician and confirmed by ELISA (and, if positive, by Western Blot).

For the ELISA test, a specimen was collected from the mother, cord blood (or baby). Counseling and testing were done at the most appropriate time. Tests were run at 6:30 a.m., 6 days a week. ELISA results were reported to the clinician (later confirmed with Western Blot, if positive).

Two large urban hospitals in Connecticut were selected for the study, which ran from January to August 2000. Eligible subjects were women who had not been tested earlier in pregnancy. Data were collected on demographic characteristics of the study participants, and on date and time of a) admission to the hospital, b) rupture of membranes, c) birth of the infant, and d) when the HIV result was available.

During the study period, Hospital "A" conducted 56 ELISA tests and 17 SUDS tests; Hospital "B" conducted 6 ELISA tests and 40 SUDS tests. About one-third of the study population were African American, one-third were White, and one-fifth were Hispanic. Ten (8.4%) of the 119 patients had a history of drug use; 7 (5.9%) had an STD during pregnancy; 28 (23.5%) had inadequate prenatal care; and a total of 37 (31.1%) had some risk factor for HIV infection.

A preliminary analysis of the timing of the availability of results includes very large standard deviations because the testing occurred in a number of atypical labor and delivery situations; further analysis is needed to refine these numbers. However, this preliminary analysis indicated that mean time to availability of test results for the ELISA was 30.5 hours (SD=17.3) from hospital admission, 28.9 hours (SD=19.96) from rupture of membranes, and 24.5 hours (SD=17.5) from birth of the child. Mean time to availability of test results for the SUDS was 11.1 hours (SD=26.5) from hospital admission, 6.5 hours (SD=26.6) from rupture of membranes, and 6.5 hours (SD=51.1) from birth of the child.

The proportion of results available before rupture of membranes was 0 for ELISA and 22.4% for SUDS; before the birth of the child was 6.5% for ELISA and 41.1% for SUDS; and within 48 hours of birth was 91.9% for ELISA and 96.4% for SUDS.

All 62 ELISA tests were negative; 54 of the 57 SUDS tests were negative, 2 were true positives, and 1 was a false positive.

We have drawn the following conclusions from our study:

- Women who had a SUDS test were more likely to receive their test result before rupture of membrane and before the birth of the child.
- There was not a significant difference between the SUDS and ELISA tests in receiving test results within 48 hours of delivery.
- Most women who had no prenatal test or who had risk factors were able to receive HIV test results within 48 hours of the birth of the child.

Therefore, using a rapid HIV test for women in the labor and delivery setting allows for "early" initiation of antiretroviral therapy to prevent mother-to-child transmission of HIV. Use of a rapid HIV test or expedited ELISA testing in the setting of labor and delivery will also allow most women who need testing to have a result within 48 hours of birth, which is the time period in which antiretroviral therapy must be initiated.

Overview of the MIRIAD Project

Marc Bulterys, Division of HIV/AIDS–Surveillance and Epidemiology, Centers for Disease Control and Prevention

The objectives of the Mother Infant Rapid Intervention At Delivery (MIRIAD) project are to:

- evaluate innovative approaches to counseling and voluntary rapid HIV testing for women in labor with unknown HIV status
- assess feasibility of obtaining informed consent during labor or soon after birth
- describe barriers to HIV testing and reasons for lack of prenatal care
- assess rapid delivery of ARV prophylaxis to late presenters
- evaluate neonatal therapy adherence; and receipt of post-natal care for women identified as HIV-infected.

The MIRIAD project is limited to institutions with relatively high HIV prevalence (0.8% - 4%) among childbearing women. There are five primary sites in Atlanta, Chicago, Miami, New Orleans, and New York City. Funding was awarded for 4 years; the project began in October 1999. The first year was devoted to protocol development and piloting; in the second and third years, the project will be expanded to other hospitals in the same geographic area. Project sites will link collaboratively with PACTG protocols.

The biomedical research priorities of MIRIAD include:

- evaluation of rapid HIV testing algorithms
- infant blood specimens to be collected—cord, neonatal, 2 weeks, 4 weeks, 6 weeks, 3 months, and 6 months
- virologic sub-studies (e.g., nasal/oral suction material for PCR detection of HIV)
- assess ART resistance among drug-naïve HIV-positive women and among infected infants
- mechanism of action of AZT and NVP prophylaxis
- adherence to neonatal therapy
- host-related genetic factors and HIV transmission.

The behavioral research issues are to:

- assess feasibility of informed consent during labor; and retention post-delivery
- determine reasons/barriers for lack of prenatal care
- measure perceived social support and psychosocial assets in mothers
- determine factors predicting foster care referral
- describe patterns of adherence to ART in women and their children
- evaluate an intervention to improve adherence to neonatal prophylaxis through a modified directly observed therapy.

At each site, a minimum of 1000 women presenting with unknown HIV status late in pregnancy will be screened using two rapid HIV assays (6000 – 8000 / year across sites). We expect each site will

identify and enroll approximately 20 – 30 HIV-1 infected women into the MIRIAD rapid intervention protocol and mother-infant follow-up (a total of 100 – 140 / year across sites). Three subgroups of HIV-positive women and their infants will be enrolled into the MIRIAD intervention protocol: a) women presenting in labor, b) late-registrant mothers ≥34 weeks of gestational age, and c) women identified with primary HIV infection.

Informed Consent Issues in MIRIAD

Denise J. Jamieson, Division of HIV/AIDS Prevention–Surveillance and Epidemiology, Centers for Disease Control and Prevention

We have faced several major challenges in obtaining informed consent from pregnant women for participation in the MIRIAD project. These challenges include:

- substantial proportion of women are recruited in labor (peripartum group 70%)
- many women had no prior prenatal care
- there is no established relationship with provider or health care system to build on
- the target population is particularly vulnerable to negative consequences of a positive test
- labor itself is physically and emotionally demanding
- focus of the woman is on anticipated delivery, alleviation of pain
- circumstances of labor amplify difficulties of pretest and post-test counseling.

A major aim of MIRIAD is to determine the feasibility and acceptance of informed consent from the women for rapid testing and evaluate the informed consent process in order to develop a more effective and efficient method for approaching women in labor and delivery. Development of this more effective and efficient method has been approached in four ways: preliminary focus groups, a pilot study, development of flip charts for use in talking with the women, and ongoing evaluation of the informed consent process.

Our preliminary focus groups suggested women may wish to defer receipt of test results until after delivery. As a result, we added check boxes to the informed consent form that allow women to be tested and treated in labor; but to receive post-test counseling after delivery.

Prior to enrolling participants in the MIRIAD project, we did a pilot study of informed consent procedures. We conducted a "mock" informed consent process for MIRIAD with 8-10 known HIV-infected women and 8-10 HIV-uninfected women in labor. We developed a series of open-ended questions for potential participants. We then looked at the subjective reaction to the informed consent process, e.g.: *Is there anything you did not like? Are there situations that would have prevented you from participating?* We also assessed participants' comprehension of the risks, benefits, and purpose of participating in the project. Finally, we did an evaluation of pain and pain medication in the labor and delivery process.

A third approach involved the development of small flip charts containing pictures with accompanying

text to be used with women in labor. These flip charts were piloted with focus groups.

Finally, we are conducting an ongoing evaluation of the informed consent process in MIRIAD. We are conducting postpartum interviews of women who accepted testing (both those found to be HIV-positive and those found to be HIV-negative) and of women who declined to be tested. Questions deal with the woman's reasons for declining or accepting the test and her comprehension of the process and its purpose.

In summary, there are major challenges in offering rapid HIV counseling and testing in labor to a particularly vulnerable group of women at a particularly vulnerable time. A major aim of MIRIAD is to find out how to best approach these women.

Update on HIV Rapid Tests

Bernard M. Branson, Division of HIV/AIDS Prevention–Surveillance and Epidemiology, Centers for Disease Control and Prevention

Since August 1999 New York State has required expedited HIV testing of pregnant women in labor or their newborns if no intra-pregnancy test result was available. Data presented at the 8th Conference on Retroviruses and Opportunistic Infections for the period October 1, 1999 to June 30, 2000 indicated that 69 mother-infant pairs in New York State had a positive expedited test: 41 true-positives as determined by EIA/Western Blot and 28 false-positives. SUDS was the initial test for 25 mothers and 11 infants; EIA was the initial test for 23 mothers and 10 infants. The reactive SUDS was confirmed in 10 mothers and 5 infants, yielding a positive predictive value for SUDS of 42%. The reactive EIA was confirmed in 18 mothers and 8 infants, yielding a positive predictive value for EIA of 79%. Four mothers and one infant had a reactive SUDS followed by a reactive EIA. All of these were confirmed, for a positive predictive value of 100% for a reactive SUDS followed by a reactive EIA.

An unexpected outcome of the new expedited testing regulations has been that HIV testing during the prenatal period has increased from 60% to 90% of all mothers in New York state since the inception of the regulations.

CDC is engaged in several efforts to increase the availability of rapid tests. It is encouraging manufacturers to commercialize rapid tests in the United States. It conducts clinical trials to establish test performance in settings of intended use. It is also evaluating the use of specific combinations of rapid tests to increase predictive value. Finally it has a "Treatment IDE" for expanded access to rapid tests.

Many candidate rapid HIV tests can use serum, whole blood, or plasma. Results can be read in 10 to 20 minutes. Sensitivities and specificities of the tests are extremely high. In one performance test with repository sera (196 HIV+, 200 HIV-), sensitivity ranged from 97.9% to 100% and specificity ranged from 94.5% to 99.5% for the five commercial tests included. In another performance test with repository

sera (206 HIV+, 194 HIV-), sensitivity ranged from 99% to 100% and specificity ranged from 98.9% to 100% for the four commercial tests included.

Performance results of four commercial rapid tests using whole blood (prospective, 341HIV+, 466 HIV- venipuncture specimens) yielded sensitivities ranging from 95.3% to 100% and specificities from 99.3% to 100%. Performance results of six commercial tests using plasma (341 HIV+, 466 HIV- persons) yielded sensitivities ranging from 96.7% to 100% and specificities from 98.5% to 100%.

Application can be made to FDA for an investigational device exemption (IDE) for products or "treatments" not yet approved. This IDE allows use of investigational tests in certain populations and situations. It requires an investigator, a protocol, and IRB approval. Manufacturers would normally request an IDE to evaluate a single test. However, under this exemption, CDC is looking at the performance of several tests in combination.

Discussion Summary

A participant asked if New Orleans was doing any point-of-care rapid HIV testing on Labor & Delivery wards. Ms. Foxworth replied that currently all HIV testing was being done in the laboratory, but that with the initiation of the MIRIAD study they were hoping to begin point-of-care testing with L&D nurses doing the testing.

A participant pointed out that the programs presented by New Orleans and New Haven were conducted in large hospitals with extensive laboratory facilities. These rapid testing strategies might be even more useful in a setting where large labs are not available, although the implementation of such programs might be more difficult in these settings.

In response to several questions, Dr. Branson clarified that a treatment investigational device exemption (IDE) is submitted by a manufacturer to the FDA for a single rapid test and that at least one, if not more, treatment IDEs were likely to be approved in the near future (i.e., 6 weeks). If approved, in order to use the rapid test, an institution would need to apply for use. This application would require a principle investigator overseeing the program, a protocol, and IRB approval from the site. It is unclear how cumbersome this process would be for the sites. The manufacturer might provide a web site to enroll the principle investigator and a common protocol. This would simplify the process. Dr. Branson also clarified that these tests, if granted a treatment IDE, would not be FDA-approved. Rather, the treatment IDE is a way to have access to an investigational device to diagnose or treat a serious condition in cases where nothing else is available (in this case there is no FDA-approved rapid test currently available).

A participant asked if the information learned from the informed consent process in MIRIAD would be applicable to non-research settings. Dr. Jamieson responded that this was the intent of the evaluation

component of the informed consent process in MIRIAD and that the investigators hoped that the information would be widely generalizable. Dr. Smith (NIDA, NIH) raised concerns about leaving the determination of whether or not women were competent/able to provide informed consent in labor up to individual providers; another participant concurred. She suggested instead providing objective criteria for who could be approached for the study. Dr. Jamieson felt that it would be difficult to determine a priori what factors would render a woman incompetent. For example, one might hypothesize that the administration of narcotic intravenous medication (e.g. IV fentanyl) would make a woman less able to comprehend the informed consent process. Alternatively, administration of a low-dose short-acting narcotic medication to relieve pain might make a woman feel more in control and better able to comprehend what is being presented.

A participant stressed the importance of partner counseling for women identified as HIV-positive through rapid testing.

Dr. Smith raised the issue that many potential participants might be accessing care at multiple sites and at different times during their pregnancy (triage, emergency rooms, alternate care settings) even though they are not registered for prenatal care. She suggested that MIRIAD collect information on this. She further stated that it was important not to ignore/disregard the community and context within which these women were living. In addition, it was important to keep in mind how this research study would be perceived in the larger non-medical community. The MIRIAD representatives all agreed that these were excellent points.

Workshop 4: Data to Evaluate the Cascade

Moderators: Mary Lou Lindegren, Stephanie Sansom, and Joy Herndon

The goal of this workshop was to share data collection efforts and data sources, and strengths and limitations of those sources to evaluate the cascade of events leading to a perinatally HIV-infected child.

PRAMS Survey: South Carolina 1995-1998

John Barnhart, South Carolina Department of Health and Environmental Control

The CDC-sponsored Pregnancy Risk Assessment Monitoring System (PRAMS) is an ongoing, population-based surveillance system that was designed to identify and monitor selected self-reported maternal behaviors and experiences that occur before, during, and after pregnancy among women who deliver a live-born infant. PRAMS data from annual surveys 1995-1998 in South Carolina indicated

that 51.6% to 58.9% of all women surveyed reported that someone talked with them about how to keep from getting HIV (39.6% to 46.7% of white women and 71.0% to 78.3% of black women). In this same period, 74.9% to 77.1% of all women reported that someone talked with them about getting their blood tested for HIV (70.3% to 74.0% of white women and 82.1% to 83.3% of black women). PRAMS Survey questions added for South Carolina in 2000 sought to find out whether women had a blood test for HIV at any time during their most recent pregnancy or delivery and, if not, their reasons for not having an HIV test during their pregnancy.

Provisional data from the South Carolina HIV/AIDS surveillance system were analyzed to determine time of mother's HIV diagnosis by birth year, 1994-2000. HIV-positive status was determined prior to pregnancy in 44% for those giving birth in 1994 with a fairly steady increase to 67% in 2000. HIV-positive status was determined during pregnancy for 33% of women in 1994 with a fairly steady decrease to 26% in 2000. The other significant trend showed 15% of women being diagnosed after the birth of the child in 1994, a sharp drop to 4% in 1995 and, thus far, 0% in 2000.

The Survey of Child Bearing Women (SCBW) is still conducted in South Carolina. We can compare the total number of reported births exposed to HIV by birth year from the South Carolina HIV/AIDS surveillance system with the number derived from the SCBW. These totals for the years 1994-1999 are (surveillance system data first): 99/108, 95/109, 73/91, 97/100, 110/102, and 81/106.

Trends in the prescription and use of AZT in South Carolina are encouraging. In 2000, all three arms of AZT (during pregnancy, during labor and delivery, and neonatal) were received or prescribed in 77% of births to infected mothers compared with just 18% in 1994. AZT was received during labor and delivery in 92% of births to infected mothers in 2000 compared to 26% in 1994. Neonatal AZT was prescribed in 98% of exposed infants in 2000 compared to 42% in 1994.

The rate of Cesarean section deliveries increased from 14% in 1994 to 63% in 2000.

Results of these preventive measures are evident in the number of perinatally acquired HIV/AIDS cases by birth year in South Carolina, which has decreased from 15 cases in 1994 to just 3, 5, and 4 cases in 1997, 1998, and 1999, respectively.

HIV Counseling and Testing Among Pregnant Women in New Jersey, 1999-2000

Linda Dimasi, HIV/AIDS Surveillance Unit, New Jersey Department of Health and Senior Services

Data from New Jersey's HIV/AIDS surveillance system is available for 191 HIV-infected women who

gave birth in 1999, and for 139 who gave birth in 2000. Data from New Jersey's Electronic Birth Certificate (EBC) system is available for all women giving birth in1999 (>110,000) and for women giving birth during the first seven months of 2000 (>62,000). It is estimated that 275-300 HIV-infected women give birth each year in New Jersey.

Matching our two data sources has revealed the following:

- Women receiving HIV counseling during pregnancy
  - Surveillance data:
    - 1999 data: 52% counseled, 43% unknown
    - 2000 data: 70% counseled, 28% unknown
  - EBC data:
    - 1999 data: 77% counseled, 12% unknown
    - 2000 data: 81% counseled, 8% unknown

- Women receiving HIV testing during pregnancy
  - Surveillance data:
    - 1999 data: 32% tested during pregnancy, 63% prior to pregnancy
    - 2000 data: 40% tested during pregnancy, 57% prior to pregnancy
  - EBC has no information on HIV testing

- Women receiving prenatal care
  - Surveillance data:
    - 1999 data: 14% received no prenatal care, 6% had 1-2 prenatal visits, 60% had 3 or more visits, and 20% had an unknown number of visits.
    - 2000 data: 9% received no prenatal care, 2% had 1-2 prenatal visits, 32% had 3 or more visits, and 57% had an unknown number of visits.
  - EBC data:
    - 1999 data: 1% received no prenatal care, 1% had 1-2 prenatal visits, 92% had 3 or more visits, and 6% had an unknown number of visits.
    - 2000 data: 1% received no prenatal care, 1% had 1-2 prenatal visits, 93% had 3 or more visits, and 5% had an unknown number of visits.

- HIV-infected women known to be aware of their HIV serostatus
  - Surveillance data:
    - 1999 data: 95% of infected women knew their positive status by delivery

- 2000 data: 96% of infected women knew their positive status by delivery
- EBC has no information on HIV status.

Pediatric HIV/AIDS cases have declined from 71 (21.1% of total exposed births) in 1993 to 22 (8.0%) in 1998. Matching of birth certificates and surveillance data has identified 81 births to HIV-infected mothers not reported to the surveillance system during this period. Matching for the years 1999-2000 is incomplete; however, data thus far indicate 9 pediatric cases in 1999 and 1 in 2000 out of total exposed births of 189 in 1999 and 140 in 2000. Six exposures have been confirmed as not being reported to the surveillance system.

Upward trends from 1993 to 2000 in ZDV during pregnancy, ZDV during delivery, and neonatal ZDV are clear. In 2000, the ZDV (PACT 076) protocol had been partly or fully implemented in about 90% of HIV-exposed births.

In New Jersey, we are also able to compare the number of children identified through the HIV/AIDS surveillance system with numbers derived from the Survey of Childbearing Women (SCBW). SCBW also documents zidovudine use.

Perinatal HIV Prevention: Assessment Tools

Aaron Roome, Department of Public Health AIDS Division, Connecticut State Department of Health

Connecticut, population 3.4 million, has an annual birth cohort of 43,000. It is estimated there are 65-75 perinatal HIV exposures per year (1.6 per 1000 births) and 2 infections per year (about 3% of exposed–1997-1999 data). HIV infection is reportable by name for children less than 13 years old; perinatal HIV exposure is reportable as of 2001, and HIV in adults is reportable without identifiers.

Under Connecticut statutes and regulations, the health department is given broad powers to investigate reportable diseases and institute special disease surveillance as may assist it in establishing adequate control measures. Under Connecticut legislation implemented in October 1999, all pregnant women of unknown HIV status are offered an HIV test. If the woman refuses, HIV testing is mandatory for the newborn.

Outcome measures for assessing perinatal HIV prevention include: (for the population of all pregnant women) the adequacy of prenatal care and the extent of prenatal HIV testing. For HIV-positive women, outcome measures for assessing prevention include: the extent of testing during pregnancy; treatment during pregnancy, labor, and of newborns and infants; the practice of breast- feeding; and testing of exposed infants. Sources of data for the assessment of perinatal HIV transmission include the following

activities by the health department's perinatal prevention program: surveillance, medical records review, birth records (includes a check box for maternal HIV), surveys of obstetricians, and audits of prenatal records. Non-health department sources include medical records reviews and interviews with women. A sampling of these data sources follows.

Vital records data for 1998 indicate that black (21%) and Hispanic (22%) pregnant women are most likely to have late or no prenatal care in Connecticut. Researchers interviewed women who had recently delivered in 1997; results published in *Obstetrics and Gynecology* (2001;97:70-6) showed that in New Haven, although 86% received information on HIV testing and 82% were offered a test, only 45% were actually tested.

An audit of prenatal/obstetric records compared percentage of pregnant women tested for HIV in 1996 (26%) to those tested in 1999 (by month of delivery). Testing increased dramatically in the last 3 months of the year (79%, 73%, and 91%), which coincided with the implementation of the mandatory newborn testing law. A survey of obstetricians in 1997 and again in 2000 (preliminary results) revealed that more than over 95% of the obstetricians interviewed had provided prenatal HIV testing to more than 3/4 of their patients. In 1997, only about 20% of the obstetricians had provided prenatal testing to more than 3/4 of their patients.

In 2000, 93% of the obstetricians interviewed said that less than 3% of their patients refused HIV testing and 88% of the obstetricians said that none of their patients delayed or interrupted prenatal care because of concerns specifically about HIV testing (4% of physicians answered that some did (8 patients) and 8% did not know). When asked about the amount of time, on average, spent on HIV counseling with each pregnant woman, 59% of the obstetricians in the 2000 survey indicated they spent less than 5 minutes, 37% spent 5-15 minutes, and 2% spent more than 15 minutes.

Connecticut conducts surveillance for perinatal HIV exposure. Active surveillance is done at pediatric clinics where a request is made for mother/infant medical records and, based on these, an enhanced perinatal surveillance form is completed. Other case finding (in order of importance) is carried out through a review of laboratory reports (on children), the birth certificate database (which has a check box for HIV), ICD9 chart reviews, SHAS interviews, and state-funded HIV counseling and testing.

Treatment with ZDV of HIV-infected women in the prenatal or labor period and of the infant in the neonatal period is also monitored. We also monitor when HIV-positive women learn their HIV status (100% of women delivering in 2000 learned of their status before (54%) or during (46%) delivery).

A final example of surveillance activities is surveillance of the rate of HIV infection in children exposed at birth. This rate has decreased sharply from 0.51 per 1000 births in 1993 to level off at 0.05 per 1000 births in 1997 through 1999.

These data suggest the following conclusions:

- HIV reporting by name, with supportive regulations, has greatly facilitated evaluation of perinatal transmission.
- Data from a variety of sources are needed to evaluate the perinatal HIV prevention cascade.
- Legislation requiring that HIV status be known during the perinatal period has resulted in almost universal HIV testing of pregnant women.

The California Prevention of Perinatal Transmission of HIV Project: Preliminary Results of Women's Questionnaires (July–October 2000)

Liz Montgomery, Department of Pediatrics, Stanford University

Preliminary results of the childbearing women's questionnaires are based on 596 responses (162 form Sacramento County, 219 from Alameda County, and 215 from San Joaquin County) of a projected 1500 total.

About 36% of the women were black, 31% were Hispanic/Latino, and 22% were white (not Hispanic). Distribution by age group was 26% (under 20), 24% (20-25), 36% (25-34), and 14% (35 or older). About 61% had a high school degree or GED, 24% had some college or an advanced degree, and less than 15% had less than a high school education.

Sixty-nine percent were insured by Medi-Cal or other government programs; 20% had an HMO paid through her own or her partner's employer; and 6% paid for an HMO out of their own pocket. Prenatal care for 86% of the women began in the first trimester and for 11% of the women in the second trimester.

In response to the question of whether they had *ever* been tested for HIV, 88.9% said "yes" and 8.9% said "no." Ninety-five percent of the women who were offered the test accepted; 2.6% declined. However, when we asked whether the women had been *offered* an HIV test during a prenatal visit, 79.2% answered "yes" and 18.3% answered "no." Ninety percent of the women who were offered the test accepted; 8% declined.

As to why they took the test (respondents could choose more than one reason), 91% agreed with the statement "I wanted to know my HIV status for my health and the health of my baby;" 24% agreed with the statement "I didn't feel like I had a choice;" and 63% agreed with the statement "My doctor or nurse told me I should take the test."

Other reasons women gave for taking the test included:

- had sex with guys who I didn't know, was raped, partying a lot
- to be sure and safe (past drug history)
- just took all the tests offered by the doctor
- maintain my well being
- better to be safe than sorry
- sister has HIV/AIDS
- to know for sure, take test every 6 months
- was feeling tired and ill.

Of those women who declined the test (more than one reason could be chosen), nearly 49% agreed with the statement "I didn't think I could be HIV infected;" 37% with the statement "I already had an HIV test, didn't want another one;" and 6% with the statement "I didn't want to know the results." Less than 3% indicated they did not feel comfortable with the way the doctor or nurse asked them to take the test.

Other reasons for declining the test included:

- because she told me other blood tests would show that I was HIV-positive or not, so I don't need the test
- just didn't need to take it
- never knew anyone HIV-positive and don't feel at risk
- too busy indulging in substance abuse.

We plan on looking at all of these variables in more depth, stratifying for demographic characteristics. We will also analyze data *within* counties, and compare one county to other counties and the rest of the State. For example, we want to know if there is a difference in the socio-demographic characteristics of women who are *offered* a test vs. those who are *not*. And we want to know the differences between the 8% of women who are *declining* to take a test and the 90% of women who are accepting.

Los Angeles County

Toni Frederick, Pediatric HIV-Infection Reporting (PHIR), Los Angeles County Department of Health Services

In Los Angeles county, we are able to use data from the CDC-sponsored Pediatric Spectrum of Disease study to assess progress and gaps in perinatal HIV prevention in the county. The county health department also conducted a series of exit interviews with prenatal patients at public and private clinics

in the county between June 2000 and January 2001 to evaluate whether perinatal HIV counseling and testing is being universally offered, as is required by law.

Data from the Pediatric Spectrum of Disease study from 1995-2000 were analyzed to determine why failures in prevention of perinatal HIV still occurred. Of 608 children born to HIV-infected mothers in the study, 10% were infected with HIV. Twenty percent of the mothers received no prenatal care; 13% were injection drug users. All three antiretroviral interventions (prenatal ZDV, ZDV during labor and delivery and neonatal ZDV) were administered to 67% of the mother-infant pairs. Seventy-four percent of the mothers received ZDV during pregnancy and 86% of infants received neonatal ZDV. As use of maternal ZDV increased over the period, rates of perinatal transmission declined. Prenatal care was highly correlated with intervention with ZDV.

Mothers of six of the 11 HIV-infected infants born between 1998 and 2000 who received care in Los Angeles county received prenatal care. Two of the infected infants were born to women who received ZDV prenatally and at labor and delivery; these cases represent treatment failure.

To evaluate whether prenatal HIV counseling and testing were being universally offered in the county, staff from the Los Angeles County Department of Health Services interviewed pregnant women after prenatal visits at public and private clinics in the county between June 2000 and January 2001.

Of those surveyed, 95% had received information about HIV and pregnancy, about one-half had received information about HIV treatment and pregnancy, and 99% had been offered an HIV test. A total of 92% accepted the test; the main reasons for refusal were that the woman had already been tested or was in a monogamous relationship. Younger women (13-19 years) were less likely to accept HIV testing than women 20 or more years of age, although statistical significance was not reached. Foreign-born women were less likely to accept HIV testing than U.S.-born women, but statistical significance was not reached. The results confirmed that, to ensure high test acceptance rates, HIV information and counseling must be an integral component of prenatal care.

On the basis of this survey and other surveys done in Los Angeles county, the following gaps in prevention of perinatal transmission were identified. For those women with prenatal care, 5%-15% were not offered testing; 8%-20% did not accept testing; others were not retested later in pregnancy; and some delivered at a different hospital (i.e., not the HIV referral hospital) where there was either no hospital policy to ask about an HIV test or AZT was unavailable. For those women with no prenatal care (7%-20% among the HIV-infected), the problem is that rapid testing of HIV infection is currently not done.

The advent of non-named (unique identifier) reporting in California will pose several challenges: a) duplication of reports within a health department (lab reports and clinician reports); b) duplication of records within the state and outside the state (patient moving, multiple sources of care); c) educating providers (monitoring of their performance, accuracy of reports); d) problems with the unique identifier itself (changing last names, errors in dates, using “0000" for social security number); e) coordination

with the PSD study (creating the unique identifier, clarifying reporting roles); f) matching babies and moms (coordination with enhanced perinatal surveillance); and g) how to address exposed babies (assign unique identifier or hold by PSD until infection status is determined).

Massachusetts

Abbie Averbach, HIV/AIDS Bureau, Massachusetts Department of Public Health

Mukachilima Chikuba, HIV/AIDS Surveillance Program, Massachusetts Department of Public Health

Abbie Averbach discussed the Medicaid Data for Perinatal HIV Prevention Project. The objective of this project is to evaluate HIV counseling and testing rates among pregnant women enrolled in Medicaid from 1999 to 2003. We are using the following algorithm for the selection of cases to be included in the project. A case is defined as a pregnant woman who did not already know her HIV status and therefore was eligible for testing during pregnancy.

The initial cut is all women currently enrolled in Medicaid in a 2-month period (November and December) for baseline year (1999) and subsequent years. From this group we will create a subset of women who delivered in those months. We will exclude women who were previously diagnosed with HIV based on ICD-10 data. Using medical care billing information going back 7 months prior to delivery and laboratory billing information going back 7 months prior to delivery, we will identify women who were tested for HIV during pregnancy. For women who have neither a medical care billing record or laboratory billing record of an HIV test, we will pull pharmacy billing records to see if any women were being prescribed drugs that would be indicative of HIV infection. Thus, the remaining subgroup is comprised of women who were not tested for HIV during their pregnancies.

Mukachilima Chikuba reported on facility-based enhanced perinatal surveillance at three hospitals. Data from the Massachusetts Pediatric Spectrum of Disease (PSD) project for the years 1996-2000 indicate the total number of births to HIV-positive pregnant women and the number of infected children in each of these years (66/8 in 1996; 79/7 in 1997; 85/6 in 1998; 77/6 in 1999, and 51/2 in 2000 –data as of February 23, 2001).

The proportion of pregnant women known to be HIV-positive, whose country of birth is outside the U.S. and U.S. Dependencies, has increased over the last two years. The proportion of babies born to HIV-positive mothers that become infected has remained fairly constant at around 8% over the period 1996-1999. Over 90% of pregnant women known to be HIV-positive received some prenatal care in each year during the period 1996-2000. Data on the 80,866 births in Massachusetts in 1999 show that 2,886 (4%) of the mothers had no or late prenatal care; 5,708 (7%) of the infants had low birth weight; 77 (1 per 1,000) of the mothers were HIV-positive and 6 of the babies (7 per 100,000) were HIV-infected. Three of the mothers of infected infants were foreign-born, one was an injecting drug user.

Surveillance program data (as of February 1, 2001) indicate that there are 3,036 women aged 13-50 living with HIV/AIDS in the state; 17% (n=527) are foreign-born. Four percent (n=123) were known to be pregnant at the time of HIV diagnosis. Injecting drug use was the primary mode of exposure in 47% of the women.

Funds for enhanced perinatal surveillance (EPS) in Massachusetts are being used to set up facility-based surveillance at three hospitals: Boston Medical Center, University of Massachusetts Memorial Hospital, and Baystate Medical Center. The three hospitals are not representative of birthing hospitals in the state in that they are referral centers for high-risk pregnancies and the catchment population for the hospitals is generally inner-city residents with lower socio-economic status and a larger proportion of immigrants. In addition, the hospitals:

- handle 13% of all births in Massachusetts
- diagnosed 30% of all women living with HIV/AIDS
- clientele have estimated 51%, 61%, and 71% adequacy of prenatal care (defined using the Kessner Index–state average is 80%)
- have higher proportions of low birth weight babies at 11%, 10%, and 10% (state average is 7%)
- handled 41% of all births to mothers known to b HIV-positive during the period 1996-2000.

Massachusetts has a non-name HIV reporting system. So the hospitals will generate a soundex for all records reviewed for EPS. Consent is required for release of records for review. PSD project staff have agreed to administer the consent process for EPS. A birth registry match for women of reproductive age living with HIV or AIDS will be reported to the surveillance program, using unique identifiers for HIV and names for AIDS.

Using Birth Certificate Data to Evaluate Prenatal HIV Testing Rates

Cheryl Jablonski, Texas Department of Health

New legislation effective January 1996 in Texas required prenatal care providers to test pregnant women for HIV at the first prenatal visit and at delivery, unless the women refuses. Three fields were added to the birth certificate in 1996: *Mother HIV tested prenatally? Mother HIV tested at delivery? Mother received zidovudine?* A survey of private obstetricians and gynecologists concerning their prenatal HIV testing practices was conducted; 99% of 614 reported offering an HIV test to all pregnant patients.

By multiplying the number of resident births by the rate of positive HIV tests in the Survey of Childbearing Women, we can estimate the number of HIV-infected women giving birth each year in Texas for the period 1992-1997. Based on a 20-25% vertical transmission rate for HIV without therapy

and an 8% rate with therapy, potential perinatal HIV cases prevented number between 36 and 60 each year during this period in Texas.

Looking at timing of HIV test and type of prenatal care provider for pregnant women in 1997, the percentage of women tested prenatally was highest for private ob/gyn's (90.0%), followed by public health clinics (83.9%) and hospital clinics (76.4%). It was lowest for midwives (59.3%) and women with no prenatal care (22.4%). When we look at women who were tested prenatally *or* perinatally, those who used midwives (78.8%) and those with no prenatal care (88.9%) were least likely to have been tested. Most likely were those attending public health clinics (97.8%), and private ob/gyn's (95.2%).

Looking at a subset of births (Harris county which includes the city of Houston) in 1999, little variation is noted in the percentage of women tested either prenatally *or* at delivery, when race and ethnicity are considered. However, only 77.4% of Hispanic women and 85.0% of African American women were tested prenatally compared with 91.9% of white women.

Workshop 5: Substance Abuse among Pregnant Women

Moderator: Ken Dominguez

The goal of this workshop was to introduce attendees to important treatment and care issues for substance-abusing pregnant women and encourage them to incorporate this knowledge into their plans for providing pregnancy testing, HIV-related counseling and testing, and HIV-related care to these women.

The objectives were:

- To discuss the barriers faced by substance-abusing pregnant women to substance-abuse rehabilitation and treatment and prenatal care services.
- To discuss the criminalization of substance-abusing women.
- To describe current state-based perinatal HIV-elimination projects geared to addressing the needs of substance-abusing pregnant women.
- To describe other programmatic efforts (federal, state, or local) related to providing substance-abuse rehabilitation to substance-abusing pregnant women.
- To encourage states to begin addressing some of the issues brought up in today's workshop in the context of their perinatal HIV elimination projects.

There were three presenters: Jo Sotheran, Ph.D ., from the Division of Sociomedical Sciences, Columbia University, Mailman School of Public Health; Karol Kaltenbach, Ph.D., Director of Maternal Addiction Treatment Education and Research, Jefferson Medical College, Thomas Jefferson University; and Ulonda Shamwell, M.S.W., Associate Administrator for Women's Services, SAMHSA.

While the three presenters represented three different institutions, they all highlighted issues that were equally important and somewhat similar. Dr. Sotheran discussed the social nature of drug use, drug users' background, and how these may influence access to treatment and services. She also highlighted the barriers to services and ways of eliminating the barriers. In an effort to provide services to drug users, especially pregnant drug users, it is important and necessary to understand the world of drug users as they see it. Drug use is a social act. Drug users are part of a social network and they operate within a social network. They are involved in a daily routine of selling and buying drugs. They are also involved in illegal activities. Many of them either come from broken relationships or suffer from broken relationships. Contrary to belief, the drug users are very focused and goal-oriented and are involved in very time consuming activities.

Drug users do not always plan for the future. Among drug users, there is a high prevalence of mental illness, including PTSD and anxiety disorders. More men than women are drug users. Women are often dependent on others for drugs or money. Many of them have experienced sexual and physical abuse. Stigma is greater among female drug users. Many female drug users are involved with another drug user. Many of them are also mothers.

There are a number of barriers to accessing the services available for pregnant, drug-abusing women. Very few drug treatment programs exclusively serve women. Providers do not always understand the issues surrounding drug abuse. Many women are faced with child-care issues. Because they fear action by the child protective services, they are not always willing to reveal their drug use. Many present themselves for services very late into their pregnancy. In order to address the issues faced by pregnant drug-using women, there is a need to focus on women-centered services, including both legal and mental health services.

Dr. Kaltenbach focused her presentation on treatment issues for substance-abusing pregnant women. She highlighted three areas: the relationship between prevention and treatment; barriers to treatment; and the complexity of the needs of substance-abusing women. In dealing with substance-abusing pregnant women, prevention and treatment should not be considered separately. There are a number of barriers to treatment. These are: lack of adequate programs for pregnant and parenting women; criminalization and prosecution of substance-using pregnant women; fear of losing custody of a child; judgmental attitudes of providers; and addiction issues, such as denial of addiction, medication of feelings, issues of control and responsibility, and viewing relapse as a failure. Additional concerns in relation to barriers to treatment are: fear of facing problems and feelings, fear of loss of partner, difficulty in coping with changes in relationships, anticipation of failure in being abstinent, and lack of social support for recovery.

Substance-abusing pregnant women have complex needs. They have various medical needs such as treatment for HIV and other STDs, anemia, hypertension, urinary tract infection, and hepatitis. They need psychiatric services and family social services. Most of them have limited education, very few marketable skills, and limited work experience. Many of them are also homeless as well as heads of households and primary caretakers. They suffer from high levels of anxiety and depression, with low levels of self-esteem. Many of them were sexually and physically abused when they were children.

Ulonda Shamwell from SAMHSA discussed various SAMHSA goals and how those affect services for pregnant women. Through SAMHSA block grants to the states (the Substance Abuse Prevention and Treatment Block Grant and the Community Mental Health Services Block Grant), the states ensure that pregnant women are given preference for treatment. Five percent of the Substance Abuse Prevention and Treatment Block Grant is set aside for pregnant and parenting women. SAMHSA has a number of programs focusing on women. While Ms. Shamwell highlighted the need for gender-specific treatment for women, she also identified a number of barriers to treatment for women. These are: stigma; lack of early identification of the problem by professionals; lack of child care and of access to children's services; lack of residential treatment programs that can accommodate mothers with children; and lack of transportation to and from treatment sessions. In addition, other barriers identified were: lack of appropriate services sensitive to the needs of women with various issues and staff attitudes towards women. SAMHSA has a comprehensive model for substance-abusing women, including outreach, intake screening and comprehensive health assessment, medical treatment and linkages and collaboration, health education and prevention, educational training and remediation, transportation, housing, child-care services, and continuing care. Intake screening and comprehensive health assessments are important tools in understanding the women's needs and developing appropriate programs.

At the end of the presentations, a number of issues were discussed and suggestions made by the states. In terms of collaboration with other programs, representatives from Chicago and Florida suggested establishing linkages between HIV prevention programs and drug treatment programs; bringing together all providers to talk about information sharing and collaboration; and conducting joint outreach by HIV and substance abuse treatment programs. A number of jurisdictions (Puerto Rico, New York, Texas, Maryland, Virginia, and Illinois) work with substance-abusing women.

The participants also discussed the need for gender-specific comprehensive programs. The need for training various providers was emphasized. In addition, there is also a need to access to various services. In Texas, both HIV prevention providers and Ryan White service providers are trained in harm reduction philosophy.

Workshop 6: Provider Training: Challenges in Implementation and Evaluation

Moderators: Sherry Orloff and Mary Kay Larson

New York State Task Force for the Prevention of Perinatal HIV Transmission: Prenatal Care Provider Training

Roberta Glaros, AIDS Institute, New York State Department of Health

David Odegaard, Downstate Medical Center, State University of New York

The objective of New York State's Prenatal Care Provider Training program (PRECARE) is to increase the prenatal HIV test acceptance rate to at least 90% (current New York State average) in facilities with lower rates. Activities to meet this objective include the selection of a training organization (in this case the Downstate Medical Center of the State University of New York at Brooklyn), identification of target facilities, and provision of technical assistance and educational programs to the prenatal care providers at selected facilities.

About 20 target facilities will be identified, based on these criteria: a) high seroprevalence areas (found chiefly in New York City); b) low rates of HIV testing; and c) high rates of expedited testing (offered at labor and delivery if women has not been tested during prenatal care and, if not done, required for the newborn).

To identify low rates of prenatal testing (<90%) and high rates of expedited testing, we will examine the maternal-newborn HIV test history data submitted (by law) by all birth facilities. These data indicate what the mother's HIV test history was at the time she presented for delivery and whether expedited HIV testing was done (on mother or newborn). From these data we will also be able to see over time any increases in prenatal testing and decreases in expedited testing at the target facilities.

David Odegaard of the Downstate Medical Center then discussed the obstacles and strategies in working with prenatal care providers under this program to improve HIV counseling and testing (C&T). Twenty-three hospitals in New York have been targeted for training; so far the Downstate Medical Center has been involved with 15 of these.

Barriers to training include:

- indifference ("HIV not our problem," "we are doing a good enough job on this")

- competing priorities (JACHO/other reviews, mergers, staff changes, overwhelmed by other health care issues)
- organizational/systems problems (miscommunication, conflicting versions of who is responsible for HIV C&T, inefficient/inadequate C&T procedures, private MDs or other health care facilities as the source focus of inadequate C&T).

We have developed multiple strategies to overcome these barriers. A letter from the Director of the New York State Department of Health AIDS Institute to the hospital CEO (with copies to OB chair, OB administrator, HIV program director, etc.) provides the initial contact with the hospital. Included in the letter are statistics on the hospital's current performance, indicating that this performance does not meet state goals.

We contact the site and offer training, emphasizing the OB Grand Rounds lecture for clinicians, "Update on Guidelines for the Reduction of Perinatal HIV Transmission," presented by an MD and credentialed for CME. This lecture also stresses that HIV C&T a) is cost effective, b) is standard of care, c) can lead to liability issues if not properly conducted, and d) is increased when physicians and midwives encourage it among their patients.

With the OB chair (or, more likely, OB nurse or administrator) we complete an in-depth needs assessment to analyze the hospital's current system of prenatal HIV C&T, including who conducts C&T, how frequently, how patients are referred, and how C&T documentation is sent to Labor and Delivery wards. Through statistics provided by the state, we do further analysis to identify where the problem is.

We then arrange a meeting with OB representatives to review findings, which are summarized in a letter that identifies the problem areas and proposed solutions, such as training additional personnel to conduct C&T, steps to improve the documentation system, steps to make C&T a more efficient procedure, or technical assistance.

We offer tailor-made HIV C&T provider training to target site personnel as needed in various settings. Training includes techniques for streamlining C&T, role playing, documentation requirements, etc.

When we have completed all interventions we have a final meeting and/or summarize our training and technical assistance in a letter. We give the site contact a technical assistance packet, which includes guidelines, required state forms, quality assurance checklists, etc.

Finally, we monitor the site for 6 months to review HIV C&T rates. If statistics indicate there has been no change or a further decline in testing rates, we return to the site for further assessment and intervention.

Five hundred fifty prenatal care providers (MDs, nurses, midwives, C&T staff) have been trained thus

far. But the project has also done much to identify problems in the entire perinatal HIV prevention system.

Discussion Summary

In response to a question about language barriers in the counseling setting, Mr. Odegaard commented that there was a need in New York to have HIV information translated into other languages. Members of the audience shared their state's experience using peer counselors and translators. In New York the most effective counselors focus on the effectiveness of the treatment, the fact that the child will be tested anyway, and the benefits to the child.

Perinatal HIV Prevention in Illinois: Assessment, Training, and Evaluation

Christopher Mitchell, Midwest AIDS Education & Training Center

This project of the Midwest AIDS Education & Training Center and the Illinois Department of Public Health has as its objectives to:

- assess current practices related to HIV testing and counseling of pregnant women and the clinical management of HIV-positive pregnant women throughout the state of Illinois
- develop training and educational opportunities for perinatal providers based on the identified needs
- evaluate changes in practice patterns after perinatal prevention training
- compare providers' self-reported prevention practices with recalled experience of postpartum women.

Four perinatal networks "downstate" (outside of Chicago) and six within metropolitan Chicago constitute the perinatal network administrative structure in Illinois. To assess needs we conducted phone interviews with key informants (perinatal network administrators) from the four downstate perinatal networks and administered a self-report survey to perinatal providers within metropolitan Chicago.

An earlier attempt to survey providers by mail in the downstate area had produced a poor response rate (21% after 2 mailings). So we asked perinatal network administrators from the four downstate networks to survey obstetricians who have rights at their facilities while many of these providers were attending a local meeting. A 60%-70% response rate was achieved. There were consistent findings across the four networks.

The provider survey in metropolitan Chicago was administered by hospital personnel to a sample of 491

providers. Data was collected through provider self-report. Findings were remarkably consistent.

Based on the needs assessments, training and technical assistance opportunities were developed. Six months later a provider self-report survey was re-administered to training participants to evaluate changes in providers' practices (only 60 have been received so far). We are also developing a postpartum survey to be used with all women at all hospitals for a 1-month period. It will ask their recollections of prenatal HIV testing and counseling. We will then compare these findings with the providers' self-report of HIV prevention-related activities. We will again be working through the perinatal networks.

We believe the success of our efforts has been due to several factors: Working within the perinatal network structure, we have made this a collaborative effort to ensure "buy-in." We solicited the network's administrators input in form development and data collection strategies. We offered the networks a modest financial incentive. We obtained official letters of endorsement for the project, e.g., from the Director of Family Health. Finally , we reported findings in an easily understandable language.

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Provider Training in South Carolina

Lynda Kettinger, South Carolina Department of Health and Environmental Control

Ryan White Title IV is administered statewide in South Carolina; this gives us an advantage with respect to disseminating treatment guidelines and providing training to prenatal care providers. We also continue to conduct (with state funds) the Survey of Childbearing Women. Still, our HIV/AIDS surveillance system indicates that 80-100 infants born each year in South Carolina are exposed to HIV.

Key indicators of the need for provider training in South Carolina are:

- percentage (75%-95%) of pregnant women tested for HIV (PRAMS, provider survey)
- percentage (95%-99%) of HIV-infected pregnant women tested before birth (enhanced perinatal surveillance)

- percentage (54%) of hospitals offering rapid testing during labor and delivery
- percentage (around 80%) prescribed all three arms of antiretroviral therapy for perinatal HIV prevention (85% in prenatal period, 92% at labor and delivery, 98% neonatal).

The South Carolina AIDS Training Network, Ryan White Title IV clinicians, and MCH Regional Systems Developers have all been involved in perinatal HIV prevention training. The last group supports outreach educators to hospitals, prenatal care providers, and pediatric providers.

The goals of our project were to: a) target the 8 counties with the highest HIV prevalence rates, b) increase awareness of the current care system and available resources, c) maintain ongoing clinical training, d) address "gaps" and missed opportunities, and e) expand the type of prenatal care providers that are trained.

Our key strategies are:

- to contract with the South Carolina School of Public Health (Training Network) to produce a resource manual for more than 3600 providers statewide
- conduct 8 hospital trainings/physician trainings in 2001
- set up mini-residencies where high-level clinicians can provide an overview of perinatal prevention strategies
- conduct regional training for labor and delivery nurses and obstetrical staff in rural settings.

Through pediatric task forces, obstetrics task force, the statewide STD/HIV conference, web page linkages, and exhibits at professional meetings, we will promote general awareness and successes of perinatal HIV prevention.

Evaluation of the project will be through process measures (number of people participating), a 6-week post-training survey to assess changes in provider practice, and a survey of practices by providers and hospitals. We will monitor outcomes of the project through enhanced perinatal surveillance data and PRAMS data to identify specific gaps.

The challenges we continue to face are getting physicians to participate in the training, updating our resources and training with constantly changing information, and staff turnover.

Workshop 7: Community Outreach: Challenges in Implementation and Evaluation

Moderator: Francis Walker

New York State Department of Health AIDS Institute: Community Action for Prenatal Care Initiative (CAPC)

Roberta Glaros and Donna Parisi

AIDS Institute, New York State Department of Health

The New York State Task Force on the Prevention of Perinatal HIV Transmission, which consists of state and city agencies that deal with HIV/AIDS (women's health, family and community health, disease intervention, and alcoholism and drug abuse programs), has set a goal of reducing perinatal HIV transmission to 5% or less by 2004. For the task force's Community Action for Prenatal Care Initiative (CAPC), community coalitions have been formed and lead agencies selected in four areas; three in New York City and one in Buffalo.

Recognizing that strategies currently in place were not reaching the target population for perinatal HIV prevention, the coalitions seek to implement a comprehensive recruitment strategy that includes social marketing, a hot line for self-referral, referrals from community agencies serving high risk women, and enhanced street outreach. The coalitions are also responsible for developing an intake process at accessible sites in the community and coordinating a network of services needed by high risk women, including "user-friendly" prenatal care. The "intake" sites do pregnancy and HIV testing and transitional case management and refer clients to the service network, including long-term case management programs.

Rather than hire new staff, the project trains existing outreach staff to provide enhanced outreach. The worker in enhanced outreach is expected to complete 5 days of training, participate periodically in coalition-sponsored outreach projects, provide enhanced outreach to pregnant women encountered during routine outreach sponsored by their home agency, respond to hot line referrals from the lead agency, and, at the request of the prenatal provider, follow up on pregnant women lost to care.

The enhanced outreach worker:

- knows the barriers that keep pregnant women from entering prenatal care
- is familiar with resources for high-risk women within the community
- is familiar with the policies, procedures and staff at designated intake and prenatal care sites

- works through the social networks of women at risk within the targeted community
- seeks to build a trusting/helping relationship with individual clients, which may involve a series of encounters over time
- focuses on the women's immediate needs as she defines them.

Special training and activities are also provided for enhanced outreach supervisors.

There have been several challenges to implementation of enhanced outreach. Coalition building takes time and effort. There is a resistance to change in outreach practices and models, which don't typically navigate people into care. The expectations of government funders may be too high initially. Training outreach workers to handle complex issues is a difficult task; issues must often be boiled down to simple concepts and practical steps for the client. There is a large turnover of outreach workers and supervisors, since generally they are not salaried employees on a career path. The final challenge is data collection.

Donna Parisi then presented an overview of how the project will be evaluated. New York State is collecting identifying information on the CAPC client up front, once she is found and brought into care either through outreach, the hotline or agency referral. They can then link with the rich sources of data already being collected to determine the following outcomes: the extent of prenatal care utilization, prenatal HIV testing, receipt of full 3-part 076 ARV regimen, perinatal HIV transmission, and birth outcomes (i.e., low birth weight).

Intermediate outcome measures include the number and percentage of women keeping their first referral appointment (information gathered through random record reviews at the sites where the CAPC client has been referred), and the knowledge, attitude, and behavior change resulting from the training of outreach workers (information collected by administering pre/post training questionnaires and a follow-up survey to determine what additional training the outreach workers need). An Intake Form has been developed to collect the following process measures: number of women completing intake form, source of intake (direct outreach, referral, media campaign, etc.), services received at intake (pregnancy testing, HIV testing, etc.), number and type of referrals provided, and number and percentage of women needing follow-up for missed referral appointments.

Challenges to evaluation include identifying the women that fit the CAPC model, obtaining identifying information at the intake site (women may not be willing to give this information), and standardizing the data collection protocol (who fills out the form? where?).

Key findings from the project thus far: a) the necessity of involving the targeted population in activities; b) ensure that the service system is established before implementing outreach activities; c) dedicating outreach workers to assist clients in navigating the system is desirable, but this will diminish the outreach workers' time and effectiveness in other activities; and d) consider the use of non-traditional setting or venues for education, for example, presenting information to women during the bus ride to Rikers Island.

New Jersey Experience

Eileen Girten and John Beil

New Jersey Department of Health and Senior Services

The New Jersey Perinatal Initiative was created to maximally reduce perinatal HIV transmission in the state. Three cities (Jersey City, Paterson and Newark) were selected based on zip code data that identified the highest pregnancy rates among HIV-infected women. The agencies in each city provide HIV, pregnancy and STD testing and other services via a mobile van. An outreach form was developed to capture essential risk factors, demographic data and services delivered. Based on 2,649 outreach encounters between inception of the program in July 2000 and January 2001, these were the key findings:

- Although risk factors identified included non-injection drug user, woman at risk through sexual transmission, sex worker and injection drug user, males made use of the services provided on the van.

- The average age of the female client served in outreach was 30.5.

- Difficulties in collecting complete race and ethnicity data were encountered initially. However, additional technical assistance and training were provided to clarify the distinction between race and ethnicity to ensure complete data forms.

- The majority of outreach encounters took place in a neighborhood/street setting, especially with the availability of the mobile vans. Services provided on the van included HIV testing and counseling. Fifty-two females received HIV counseling and testing with three HIV-positive results. Surveillance is aware of those cases and is conducting a follow-up at present while the agencies are providing additional services to those clients.

- Over half of the outreach encounters involved a referral, primarily to more intensive services such as health education/risk reduction and prevention case management.

- Challenges in the coming year will be to increase HIV counseling and testing, STD testing, and pregnancy testing.

Illinois (Chicago) Experience

Michael Hunter and Margarita Reina
Chicago Department of Health

The project focus is on women not engaging or utilizing services in Chicago. Outreach is conducted in several neighborhoods and in Cook County Jail. Neighborhood outreach is conducted on the streets and from door to door. Women released from Cook County Jail are referred for services and tracked. The project utilizes transitional groups, sponsored by CBOs , to assist in developing a discharge plan for the women.

HIV Prevention for Incarcerated and Formerly-Incarcerated Women

Lori de Ravello, Division of Reproductive Health, Centers for Disease Control and Prevention

Public health interventions in correctional facilities are important for several reasons:

- Incarcerated people are at high risk for STDs, TB, HIV, and mental health problems.
- Correctional facilities are the primary source of health care for many arrestees and inmates.
- Interventions in jails and prisons can have high public health impact, as almost every inmate returns to their community.

Correctional facilities include jails and prisons. Jails are short-term facilities usually operated by a city, county, or local government. Typically they hold arrestees awaiting trial or sentencing and inmates convicted and sentenced to less than one year. Fifty percent of arrestees are gone within 48 hours. Public health interventions must happen quickly or not at all. Most jails do very little screening–usually only for TB, sometimes for STDs, sometimes for pregnancy, rarely for HIV.

Prisons are longer-term facilities usually operated by the state or federal government. Here there is a greater opportunity to implement long-term public health interventions with follow-up. Prisons have a very comprehensive medical intake process, but the level and quality of ongoing medical care varies. Approximately 19 state Departments of Corrections have mandatory HIV testing of inmates upon entry into the facility; others vary in their policies.

In 1999, there were 90,668 female inmates in state and federal correctional facilities with the largest numbers in Texas (12,502), California (11,368), Florida (3,820), and New York (3,644). Incarceration

rates for these female inmates were highest in Oklahoma, Texas, Louisiana, Mississippi, Nevada, and Hawaii.

The prevalence of AIDS (0.5%) in prisons and jails is more than 5 times that of the general U.S. population. The prevalence of HIV infection in prisons (2.3% –3.0%) and jails (1.2%–1.8%) is around 8-10 times and 4-6 times, respectively, of the rate in the general U.S. population. Seventeen percent of the total U.S. population with AIDS were released from prisons or jails in 1996; 13.1%–19.3% of the total U.S. population with HIV infection were released from prisons or jails in that same year.

In 1997, pregnancy testing of inmates in state and federal correctional systems was routine in 45%, on request in 84% and "as indicated" in 100%. In city and county systems, testing was routine in 29%, on request in 93%, and "as indicated" in 95%.

In that same year, HIV testing for pregnant female inmates in state and federal systems was mandatory in 45%, routine in 84%, offered in 100%, and "on request" in 14%. In city and county systems, testing for these women was mandatory in 29%, routine in 93%, offered in 95%, and "on request" in 22%. Ten percent of these systems had no policy on this issue.

Challenges to collaboration between correctional facilities and the public health establishment include:

- different priorities (security vs. health care)
- need for public health staff to remain objective and neutral, and not aligned with inmates or correctional staff
- flexibility and understanding on the part of public health staff
- commitment of resources
- space and confidentiality issues within the correctional system setting, and
- gaining approval for studies from institutional review boards.

Overcoming these challenges will require will require outreach projects to:

- invest significant time in planning and training public health staff, correctional staff, and outreach project staff
- tap into various public health resources
- develop respectful relationships and trust among inmates and correctional staff
- build infrastructure
- learn from other successful collaborations, and
- know the rules and regulations of the institutional review boards and be meticulous and patient.

HIV prevention for women released from correctional facilities involves discharge planning, insuring continuity of care (linkages and referrals), insuring access to HIV medications, and follow-up strategies based on the women's destination–whether it be release into the community, parole, probation, or transitional housing.

In 1997, a survey indicated that 92% of state and federal prison systems and 76% of city and county jail systems provide discharge planning for HIV-positive inmates that includes referral for various medical, social and psychosocial services. Although state and federal prison systems frequently (61%-78% depending on the service) referred discharged HIV-positive inmates to a variety of medical, social, and psychosocial services, they rarely (22%-35% depending on the service; only 1% made an appointment related to HIV medications) made the appointment for the inmate. The percentages for city/county jail systems for referrals (46%-66% depending on the service) and making appointments (17%-32%; 7% for HIV medications) are significantly lower. Referrals are obviously easier to make; however, it is likely that discharged inmates will feel more of a commitment or responsibility to keep an appointment that is actually made for them. Referrals may be ignored by the inmate for a variety of reasons.

Workshop 8: Engaging Health Care Providers

Moderator: Carolyn K. Burr

Engaging Providers in Perinatal HIV Prevention: The New Jersey Experience

Sindy M. Paul, Division of AIDS Prevention and Control, New Jersey Department of Health and Senior Services

New Jersey's cumulative total of 41,290 AIDS cases ranks fifth in the U.S. It has the highest proportion of cases in women at 28%. Its 743 cumulative pediatric AIDS cases are the third highest total in the U.S.

In the state, 25% of HIV-infected pregnant women do not access prenatal care. More than 90% of providers offer HIV testing to pregnant women; more than 90% of the women who are offered testing accept it. Ninety-one percent of HIV-infected pregnant women know their serostatus prior to delivery (4% tested at delivery). Use of antiretroviral therapy has increased from 8.3% in 1993 to at least 67% in 1999.

Perinatal transmission of HIV has decreased from 21% in 1993 to less than 8% in 1999 (9 children infected 1999, 1 infected 2000--preliminary data). However, 40% of the mothers of the infected children had no known prenatal care. Women presenting in labor whose HIV serostatus is unknown to the provider represent a major gap in perinatal HIV prevention efforts.

However, there are options for dealing with this problem: rapid HIV tests, and several short-course therapy options.

We surveyed 12 acute-care hospitals in Essex, Hudson, and Union counties about their management of pregnant women of unknown HIV serostatus who present for delivery. Six of the nine respondents provide obstetrical care; only one had the capability for rapid HIV testing. Three (50%) of the six hospitals that provide obstetrical care always or almost always offer HIV counseling and testing services during labor; two rarely or never offer these services during labor. None had a policy for rapid HIV testing or short-course therapy. Five of the six use the standard EIA with confirmation by Western Blot; one uses the HIV DNA polymerase chain reaction (PCR) assay. The problem with these standard tests is obtaining results within 72 hours so that the infant can be treated effectively with ZDV.

To correct this situation, we decided to develop a statewide policy for management of pregnant women of unknown HIV serostatus who present for delivery. To do this our plan was to identify and involve providers and other stakeholders, educate these stakeholders as to the problem, develop a statewide policy for use by hospitals, disseminate this policy and the rationale for it, implement the policy, and evaluate its effectiveness.

We considered stakeholders those who would implement the policy or those who would have to give permission for, or encourage acceptance of, the policy. We used several sources to identify these stakeholders. To educate them concerning the issue, we ran a series of articles in AIDSline, a statewide publication on HIV and AIDS news. We also conducted roving symposia, presented at half-day statewide conferences and our Physicians 2000 meeting and published an article in *New Jersey Medicine* as well as information on our web site.

Our initial groundwork in policy development was through individualized meetings and informal discussions with major stakeholders: the obstetrical society, pediatricians, providers at Ryan White Title IV sites, MCH consortia, Medicaid providers, the state health department and the Academy of Medicine of New Jersey. This was followed by a meeting of all stakeholders at the New Jersey Department of Health and Senior Services where we presented the needs assessment; identified common concerns and goals; discussed potential strategies, including a statewide policy; and discussed potential barriers such as cost and test availability and capability.

All stakeholders were invited to provide draft policies; draft policies were combined into one policy by state health department staff and distributed. After discussion and revision of the draft, we will provide an educational program on the issue prior to the next policy discussion. This will be followed by finalization of the policy.

Obstetricians, pediatricians, and the state health department plan to collaborate to contact obstetric and pediatric hospital chairpersons about the new policy. The strategy and policy will be presented to both state chapters of the Association for Professionals in Infection Control and Epidemiology, and information will be mailed to hospital administrators, obstetrical chairpersons, pediatric chairpersons, and infection control practitioners. Other educational efforts will be launched through the Academy of Medicine of New Jersey and the AIDS Education and Training Center, as well as through collaborations with MCH consortia, ACOG, the Obstetrical Society and the Nurse Midwives association.

To implement the policy we will collaborate with the state hospital licensure staff, who may mail information to hospital administrators, obstetrics chairs, pediatric chairs, and infection control practitioners. If possible, a presentation will be made to hospital staff as part of a licensure update meeting.

There are several potential barriers to implementation of the policy:

- cost: New Jersey law already required mandatory counseling and voluntary testing of pregnant women so we are substituting one test for another
- test availability: 6 rapid tests in FDA; SUDS discontinued
- must test be done by lab?: JCAHO requirement
- volume of testing required:
  - unknown serostatus (not all 120,000 women who give birth in any year)
  - one hospital reported doing 30 per year
  - estimated 1,100-1,200 women (1% based on electronic birth certificate data) women with no prenatal care annually statewide
- considered for women who test negative early in pregnancy.

To evaluate the implementation and effectiveness of the policy we intend to: a) repeat the questionnaire survey; b) gather information from hospital surveys; and c) look at surveillance data for women presenting with unknown serostatus (number of positive rapid tests, number given short course therapy, number of children who serorevert, and number of children infected).

Discussion Summary

An infection control practitioner (ICP) in the audience added that before sending a letter to hospital administrators about implementing a policy for rapid testing in their hospital, you should contact the hospital ICP because your letter will be sent to the ICP for a decision. Moreover, the ICP may be interested in rapid testing for assessment of health care workers who have had needle-stick injuries.

It is much more effective to have obstetricians (vs. pediatricians) engage or educate (or assist you in engaging or educating) obstetricians. Similar situation using pediatricians engaging or educating pediatricians.

In Connecticut, the hospitals applied a lot of pressure on the obstetricians to test the women before they came in for delivery.

One concern was how to do appropriate counseling before testing in the labor and delivery unit.

One person commented that it is remarkable to be able to get the committee together and that this may pose a potential problem.

Using Education to Engage Providers in Reducing Perinatal HIV Transmission

Carolyn K. Burr, National Pediatric & Family HIV Resource Center

Connie Thompson, Division of Infectious Diseases, University of Mississippi Medical Center

Clara McLaughlin, Administration for AIDS, District of Columbia Department of Health

National Pediatric & Family HIV Resource Center

The goals of the National Pediatric & Family HIV Resource Center (NPHRC) project are to: a) increase providers' knowledge about HIV counseling and testing of pregnant women; and b) increase providers' understanding of strategies to reduce perinatal HIV transmission. The provider education model that we have chosen to employ consists of faculty training, or the "train-the trainer" model. It pairs interactive educational strategies with didactic presentations and delivers "enabling" strategies to facilitate change in provider practice.

The faculty training model: a) builds on the expertise of practicing clinicians; b) uses a standardized curriculum and training materials to minimize the burden on the faculty and to ensure quality; c) is an effective way to educate large numbers of providers; and d) leaves ongoing expertise in the community.

The goal of the training is to increase women's health care providers' knowledge of and skill in:

- HIV counseling and prevention education
- interpretation of HIV tests

- management of HIV in pregnancy
- strategies to reduce perinatal HIV transmission
- referrals to HIV experts and support services in their region.

Four areas will be targeted over 2 years. NPHRC partners with key state organizations who are asked to assist with publicity, help identify and recruit providers to be trainers, co-sponsor the faculty training, and assist in scheduling speaking engagements. A state advisory committee is established, consisting of Ryan White Care Act and CDC-funded projects, state HIV/MCH leadership, and the local or regional AIDS Education and Training Center. Local HIV/OB/womens' health providers are identified for participation in the faculty training. These in turn will conduct educational programs for other healthcare providers, who use their new knowledge and skills in dealing with pregnant women living with HIV.

The first two areas we focused on were Mississippi and the District of Columbia. The first step was identification and involvement of stakeholders. Local needs and issues that impact on providers, the influences of geography, and HIV prevalence among women and community perceptions were analyzed in developing intervention strategies.

Mississippi

In Mississippi, statewide networking has brought together the Delta AIDS Education and Training Center (AETC), the Mississippi Department of Health's HIV/STD programs, the University of Mississippi Departments of OB/GYN and of Continuing Education, the March of Dimes, the HIV Rural Area Network, the Primary Care Association, the Perinatal Association, and the Mississippi Nurses Association. We have also identified the public health districts in the state most in need of this provider education.

We have discovered several major barriers to engaging providers in reducing perinatal HIV prevention. Providers themselves are reluctant to care for clients with HIV/AIDS, considering them not part of their practice. Those who are willing to provide care need support, e.g., people they can call for referrals or to get answers to their questions. The trainers themselves may lack confidence or experience as trainers. There are also barriers in the health system. Some clients lack access to care, either because they have no insurance coverage or because it is difficult to find providers within their geographical area. Urban hospitals may be experiencing financial ills and thus reducing maternal-child transmission of HIV may not be a priority.

Lessons learned thus far are to: a) involve local HIV and MCH leadership in the process; b) utilize local strengths and recognize unique constraints; c) build on existing structures and networks; and d) provide both educational and financial support for trainers.

District of Columbia

We considered several factors in identifying and involving our District of Columbia (D.C.) stakeholders: a) restructuring of the Department of Health under a new Health Director had created a health promotion cluster for new cross-agency and joint initiatives; b) building on existing networks; c) building on existing expertise; d) linking to existing program initiatives; e) addressing training in context of D.C. policy-making; and f) ensuring participation of historically under-served and emerging groups. This resulted in a steering committee consisting of the Department of Health's HIV/AIDS Administration and Maternal and Child Health Administration, NPHRC, the National Minority AIDS Education and Training Center (AETC), D.C. General Hospital (largest public provider for HIV-positive women, and Children's National Medical Center (CNMC) and Ryan White Title IV partners.

The first recommendation from the Steering Committee was to form a clinical advisory group for the initiative. This advisory group drew members from the local AETC, local ACOG leaders, consortia of clinics, public hospitals and a Medicaid managed care provider. This group was already engaged with clinical providers, could influence policy, had a history of involvement, could identify prospective faculty, and represented under-served populations. They are to assist in developing standards of care and obtaining endorsements from the provider community and from health directors.

Development of the train-the-trainer program is complicated by the fact that the operational structure for the Perinatal HIV Prevention Project is also changing and evolving at this time. However, planning for the train-the-trainer program has helped consolidate some of our committees and to reinvigorate committees and workgroups that had been previously established to address perinatal HIV. Prior to this, the project did not have the resources to address or fully implement clinical provider training. To ensure input from health care providers who would be the ultimate target of the training, a sub-committee (Title IV providers) was formed to identify training needs and to review the curriculum.

Local needs or issues that impact providers of care for pregnant women are these:

- high incidence jurisdiction (in 1999 D.C. had highest AIDS case rate in the nation compared with states or other MSAs)
- HIV surveillance system is pending (but from other studies, estimated seroprevalence rate for childbearing women is 6-7 times the national average)
- although data show that the number of children infected annually has decreased recently, perceptions about the epidemic have not changed
- debate over whether to "legislate" standards of care, and
- instability in public hospitals (in 2-year period two hospitals serving women in the neediest and most under-served communities have threatened closure).

Our next steps are to fully integrate the train-the-trainer steering committee as part of the overall

Perinatal HIV Prevention Committee structure, obtain endorsements of standards of care, and increase targeted outreach to pregnant women, especially across Department of Health agencies. We will coordinate training activities with the National Minority AETC and try to be much more targeted in our efforts (if we do this one more time). We will also assess trainees who have been through the program. Finally, we will continue to link with other urban centers through the CityMatCH perinatal HIV Urban Learning Cluster.

Discussion Summary

Instead of establishing a DOH committee, D.C. built on existing networks in the community, including historically under-served populations. One of the barriers in engaging providers was that the Medicaid agency was reorganizing and could not participate when D.C. established the committee. Also involved were the local ACOG chapter and non-profit clinic consortia.

Mississippi added training components to existing courses for physicians, nurses, etc. Physicians get CME credits for being trainers; participants get CMEs if they apply for it well enough in advance. Having colleagues do the training should reduce the reluctance barrier. Also it's very important to use "champions" (opinion leaders).

The training symposia in both DC and Mississippi involved key HIV experts from the universities whom the future physician and nurse trainers could call. Moreover, they gave pocket-size cards to participants with the telephone numbers of the experts and a web site from which to obtain information.

The March of Dimes arranged facilities for the training in Mississippi.

Workshop 9: Collaboration Between Programs for Prevention and Elimination of Perinatal Infectious Diseases Workshop

Moderators: Mary Lou Lindegren, Tasneem Malik, and Stephanie Schrag

The goals of the workshop were to share information on surveillance and prevention programs targeted at perinatal infectious diseases and to encourage collaborative efforts.

Perinatal Hepatitis B Prevention Program

Tasneem Malik, Immunization Services Division, National Immunization Program, Centers for Disease Control and Prevention

To understand the problem of perinatal hepatitis B (HBV) in the United States, consider the following:

- 24% of chronic hepatitis B infections in the U.S. are due to perinatally acquired infections
- CDC estimates approximately 19,000 births to HbsAg-positive women annually (state programs are currently identifying only 9,000 because of variation in state reporting requirements)
- perinatal transmission is very efficient: for only HbsAg-positive women, 20-40%; for HbsAg- and HbeAg-positive women, 70-90%
- 90% of infants who acquire infection perinatally become chronic carriers; 25% of them will die from liver failure due to HBV infection
- 55% of HBV-exposed births are to Asian women, 20% to African Americans, 10% to Whites, 6% to Hispanics, 9% other.

The key components of perinatal hepatitis B prevention programs include:

- screening for HbsAg, the critical first step in identifying potentially exposed infants (currently about 95% of pregnant women are screened for HbsAg)
- reporting of all HbsAg-positive women to health department
- post-exposure prophylaxis at birth
  - infants exposed at birth--administer HBIG and first dose of hepatitis B vaccine within 12 hours of birth
  - high risk of chronic HBV infection
  - potential continuing risk within household

- high degree of communication required between obstetricians, gynecologists, hospitals, laboratories, pediatricians and health department
- case management and tracking to ensure:
  - immunoprophylaxis at birth
  - completion of 3-dose vaccination series by 6 months of age
  - post-vaccination serologic testing
  - identification and vaccination of susceptible household contacts and their sexual contacts.

Hepatitis B infections are sometimes asymptomatic (the infection may not show up for years). Thus, disease surveillance will not always detect infections. Adverse outcomes (e.g., chronic liver disease) of hepatitis B infections do not occur for many years.

Effective strategies to identify, treat and follow-up infants born to HbsAg -positive mothers include:

- screening all pregnant women
- enhanced case management of infants to include:
  - contacting HbsAg-positive woman before delivery
  - informing pediatrician and delivery hospital of maternal HbsAg status
  - computerized tracking to ensure appropriate and timely post-exposure prophylaxis
- multiple reporting systems
- persistence and dedication.

A proportion of the target populations for perinatal HBV and HIV prevention programs share similar risk factors. There are also similarities in reporting mechanisms and transfer of information. Some potential links between these programs include:

- integration of assessment/monitoring activities
  - adapt hepatitis B screening audits to include screening for HIV and other perinatal diseases (implemented in Delaware, Massachusetts and Maine)
  - adapt newborn metabolic screening card to include maternal HIV and HbsAg results
- collaboratively work with birthing hospitals to establish treatment protocols; written and/or standard policies for screening, immunoprophylaxis and treatment
- structural integration of the programs in health departments--allows use of funding from different sources, i.e., “loosening up” categorical funding (implemented in Connecticut).

Syphilis Elimination Program: Congenital Syphilis

William C. Levine, Division of STD Prevention, Centers for Disease Control and Prevention

Congenital syphilis results from infection of the fetus by *Treponema pallidum*. For 4 years after acquiring syphilis, the probability of transmitting infection to the fetus is greater than 70%. Forty percent of pregnancies in women with untreated early syphilis end in perinatal death. Infected infants that survive can develop acute systemic illness, bone deformities, blindness, or deafness. Congenital syphilis may be prevented by treating infected pregnant women with penicillin.

A study of syphilis among HIV-positive mothers and their infants in Houston and Dallas, Texas, 1988-1994 revealed that:

- 816 infants born to 718 HIV-positive women
- of the 718 women, 127 (18%) had been diagnosed with syphilis
- 97 infants (12%) were born to mothers with syphilis during pregnancy
- 49 infants (6%) were reported to have congenital syphilis
- among women with HIV infection, characteristics associated with syphilis included black race, being unmarried, and use of injection drugs.

A study of mortality associated with congenital syphilis in the United States, 1992-1998 showed that :

- from 1992-1998, 14,627 cases of congenital syphilis were reported in the United States
- 760 stillbirths were reported, and 182 deaths within 3 months of birth
- 71% of mothers of infants who died were documented to have untreated or inadequately treated syphilis before or during pregnancy
- 52% of deaths occurred before 30-weeks gestation
- to prevent deaths, treatment needs to occur by mid-second trimester.

An infant born to a woman with untreated or inadequately treated syphilis at delivery constitutes a presumptive case of congenital syphilis (case definition, 1988). Laboratory confirmation of *Treponema pallidum* infection in the neonate constitutes a confirmed case.

An analysis of 801 case reports of congenital syphilis in the United States in 1998 identified the following reasons for vertical transmission:

- 651 (81%) of the infants were born to women with untreated or inadequately treated syphilis before or during pregnancy; of these, 233 (36%) received no prenatal care
- 91 (11%) were born to women with equivocal serologic response to therapy; 30 of these had clinical evidence (X-ray or CSF) of congenital infection;
- 59 (7%) were born to women with evidence of treatment failure or reinfection.

Current strategies for syphilis elimination include:

- outside of the South, focus on urban areas; in the South, include urban and rural populations
- develop strong elimination programs in areas considered to be at high risk, even if they now have low rates of disease
- strengthen surveillance, outbreak response, and control measures for areas with persistent and reemerging syphilis
- develop community partnerships to improve access to, and facilitate collaboration with, communities at high risk for infection.

At a meeting in April 2000 on syphilis surveillance, several recommendations concerning surveillance of congenital syphilis emerged. First, CDC should promote and provide training in the standard use of the congenital syphilis case classification algorithm. Health departments should use congenital syphilis case reporting to evaluate missed opportunities for care of pregnant women. Finally, risk indicator information such as drug use and access to care also should be collected.

Potential areas for collaboration between those seeking to prevent congenital syphilis and those seeking to prevent other perinatal infectious diseases include: a) outreach to persons and communities at high risk for HIV and syphilis; b) screening and case-finding for multiple diseases among women at risk; c) case-finding among pregnant women, and d) strengthening coverage and quality of prenatal care.

Group B Streptococcal Prevention Program

Stephanie Schrag, Division of Bacterial and Mycotic Diseases, Centers for Disease Control and Prevention

There has been a 70% decline in early-onset group B streptococcal (GBS) disease from 1989 to1999. One in four women is a carrier for GBS.

The U.S. consensus recommendations (CDC ’96, ACOG ’96, AAP ’97) for GBS advocate either one or the other of these two approaches:

- Screening-based approach: do screening at 35-37 weeks gestation; offer intrapartum antibiotic prophylaxis to women delivering preterm babies and to GBS carriers; or
- Risk-based approach: intrapartum antibiotic prophylaxis to women delivering preterm, to women with duration of membrane rupture 18 hours or longer, or to women with intrapartum fever (temperature of 38 degrees Celsius or above).

An audit of birth records was recently conducted to assess compliance with perinatal infectious disease prevention guidelines (focus on prenatal testing); to re-evaluate perinatal GBS prevention guidelines; and to develop a tool that can aid states or other groups interested in evaluating perinatal disease prevention activities and help them foster an environment for integration of these activities.

A random sample of maternal delivery medical records for 1998 and 1999 births in the Active Bacterial Core Surveillance/Emerging Infections Program Network were reviewed. Besides GBS information, the following is a sample of the information collected:

- HIV: prenatal testing, testing on admission, maternal IV drug use (during current pregnancy or lifetime)
- hepatitis B: prenatal testing, testing on admission, test result, documentation of infant birth dose in maternal chart
- syphilis: prenatal testing, testing on admission, test result, type of test (RPR, VDRL, or FTA).

The study is still ongoing, but we anticipate the following study products:

- recommendations for improved compliance with prevention protocols
- re-evaluation of perinatal group B streptococcal disease prevention guidelines
- improved integration of perinatal prevention programs.

Congenital Rubella Prevention Program

Sue Reef, Epidemiology and Surveillance Division, National Immunization Program, Centers for Disease Control and Prevention

The rubella vaccine was licensed in 1969. Rubella infections are at record low levels with less than 300 cases per year being reported currently. The majority of cases are among foreign-born adults. Outbreaks in 1996 through 1998 were work-associated in more than 50% of the cases; the cases were not usually found among U.S.-born individuals. Since 1993, less than 10 congenital rubella syndrome (CRS) cases per year have been reported. Fifty percent of those were preventable. Since 1997, more than 90% of

CRS cases were in infants of foreign-born women.

Prenatal testing and postpartum vaccination have been recommended for more than 2 decades. A recent study by Barth, et al. found that only 21% of hospitals had rubella immunization programs, even though this is the standard of care. Not many states laws mandate prenatal testing for rubella.

Opportunities for screening for multiple diseases:

- during the prenatal period, women should be screened for multiple infectious diseases;
- either during pregnancy or at the time of delivery, the infant can be assessed; and
- for rubella, rubella-susceptible women should be vaccinated prior to leaving the hospital (one dose of vaccine is effective).

States' Experience with Integrating Perinatal Infectious Disease Programs

Richard Holmes, HIV/AIDS Surveillance, Alabama Department of Public Health

Kathryn Arnold, Georgia Division of Public Health

Richard Holmes from Alabama presented information on ways these various programs could be integrated. As an example, he matched the data from HARS with the Artemis database that contains perinatal hepatitis B information. He matched on date of birth and last name. He found 8 women from the Artemis database that were co-infected with HIV. Those 8 women gave birth to 25 children between 1991-1998.

Kathryn Arnold from Georgia presented information on improved collaboration between epidemiology staff and program implementation staff around the perinatal hepatitis B program. To improve prevention of perinatal HBV, an HBV registry was established in 1998. Data from the registry are shared between epidemiology and program staff. For women ages 15-45 with HBV, program staff ask regional health districts for information regarding pregnancy. The goal is to educate women and notify birth hospitals to ensure timely prophylaxis for the infant.

The perinatal HBV prevention program was audited for the year 1999. CDC estimates 300 or more HBV-positive women in Georgia get pregnant each year. In 1999, 102 HBV-positive pregnant women were reported to the program. The audit linked1998/1999 HBV-positive women ages 15-45 in the registry to 1999 mothers in vital records data. There were 182 matches; 39 were in the HBV program.

These data were used to look at the program district by district in the state of Georgia. The numbers

matched were compared to the number enrolled in the program. They were able to identify weaknesses in the referral program. Appropriate measures were taken to work with the districts with weaknesses to improve enrollment in the HBV program.

Workshop 10: Case Management: Challenges in Implementation and Evaluation

Moderator: Judith Gendler Epstein

Central Pennsylvania

Patricia Fonzi, Pennsylvania Department of Health

Data from the Survey of Childbearing Women indicated an increase in the number of HIV-infected women in Pennsylvania counties outside of Philadelphia. STD surveillance data also indicated problems. Although our request for Title IV funds was unsuccessful because our numbers weren't large enough, we did get an increase in Title II funding.

We decided to link prevention of perinatal HIV efforts to programs providing care for those with HIV infection or AIDS. The majority of care programs are with social service providers; our main focus was on WIC clinics, family planning clinics, and medical facilities that participate in Pennsylvania's Medical Assistance Program.

We modified Philadelphia's Circle of Care Program (under Title IV), which provides "one-stop shopping" for mothers, children, fathers, etc. We set up comprehensive care clinics in two area hospitals and the largest AIDS service organization outside of Philadelphia. In these clinics, mothers and their partners and their children can all get treatment (mothers are often more likely to seek care for their children than for themselves; these clinics can deal with both mothers and children). Clinics have a pharmacy on-site and provide car seats, nutritionist services and adult and children's case management services (usually done by social workers). To date the clinics have seen 35 HIV-infected pregnant women; none have transmitted the infection to their newborn. Women from 22 counties are being seen in Harrisburg; plans are to start "roving" clinics at some point.

Recently we have been getting some evaluation data on our case management efforts. Based on self-reports and the use of a survey tool designed for women to discuss how and when they take their medicines, we are seeing an approximately 85% adherence rate. One problem we are encountering is

that clients, on average, move 2.5 times per year. This is because there are significant problems with substandard housing, the first wave of welfare-to-work clients, women moving out of their current residences as they enter recovery, and migrant workers. Thus, we are trying to get clients into adequate housing. Another issue is linking women with WIC providers, especially for education around breast-feeding.

Missed opportunities remain; many rural areas are not being reached and other competing needs of these women (for housing, food, etc.) mean they are sometimes lost to follow-up. In addition, there was some concern expressed over confidentiality since name-based HIV reporting will soon be implemented in Pennsylvania.

Case Management in Three Major Metropolitan Areas in New Jersey

Steve Saunders and John Beil

New Jersey Department of Health and Senior Services

Steve Saunders led off. Surveillance staff from the New Jersey Department of Health and Senior Services provided relevant data, by zip code, to enable us to target our perinatal HIV prevention program in three major metropolitan areas: Newark, Jersey City, and Paterson. Health care providers who functioned as the lead agencies were identified in each city.

A mobile van was purchased for outreach activities. Staffing the van were a driver and a prevention case management (PCM) counselor. "Foot" outreach workers from local HIV prevention grantees also go out on the van.

Prevention case management services offered on the van include: risk assessment; Ora Sure testing; limited STD screening (urine test); pregnancy testing (urine test); referral for prenatal care, STD treatment, and drug treatment; and referral into ongoing group-level interventions and individual-level interventions at HIV prevention partner agencies. Vans can drive clients to the health clinic for blood testing if necessary.

Data collection for evaluation of the project has required a huge investment of time and energy. A staff member from the prevention unit went out to sites to discuss data collection. We feel we have good data starting in October 2000. In 5 months, 50 women, 18-48 years of age, have received prevention case management services. Eighty-six percent of the women were black; 7 women were tested for pregnancy, one was pregnant. The populations targeted for PCM services are as follows (frequency in parentheses): women at risk (31); non-injection drug user (16), injection drug user (10); sex worker (5), and others (4).

A PCM session consisted of the following topics (frequency in parentheses): HIV overview (40); STDs (15); prenatal care (7); male/female condom usage skill (7); safer needle usage (1); and drug treatment (1). Referrals made during the PCM session included: doctor/provider for ongoing, routine health and medical services; gynecological services; prenatal care services; STDs; drug treatment; TB; social services; food or meals; and clothing for self/children/other family members.

Obstacles that had to be overcome included:

- acquisition of vans and getting them on the road (took up to one year; sending back to factory to be "reworked")
- the universal obstacle in 2001: insufficient staffing
- coordination of van schedules between agencies
- knowing where to do outreach
- collecting uniform data that could be linked to HARS registry, and
- identifying outcome measures.

Overcoming obstacles required time. It also required adaptation. PCM has been an established individual level intervention in New Jersey for 4 years; it had to be adapted for this setting. We also had to adapt existing process data collection instruments. Finally, it took collaboration with local perinatal workgroups and between the prevention and surveillance units at the state health department's Division of AIDS Prevention and Control.

The model for collaboration within the health department is what I call the surveillance sandwich: outreach and PCM on two slices of data. Surveillance tells prevention where to go, prevention goes there, and surveillance tells prevention how we did.

John Beil then expanded on the prevention-surveillance collaboration in New Jersey. I call it "preveillance," that is, prevention and surveillance working together toward the same goal: the elimination of perinatal HIV transmission. Surveillance and prevention don't speak the same language and our perspectives are different. Listening to each other is the key (stay away from jargon and keep it simple!). We both must focus on the "prize," getting moms into prenatal care. Evaluation (looking at where you started and at where you are now) is critical; New Jersey will conduct evaluations probably annually beginning with the year 2000.

Surveillance staff provided data to all three local perinatal prevention workgroups from: a) the 1998 Survey of Childbearing Women (data can be looked at by zip code); b) 1992-1999 HIV/AIDS Reporting System (HARS); and c) the 1993-1999 Surveillance to Evaluate Perinatal Prevention (STEP) project. This enabled us to provide data on:

- number of births, number of infants HIV-positive, and number tested for and administered ZDV, by zip code
- demographic characteristics and ZDV use in HIV-positive pregnant women
- pediatric HIV/AIDS cases and exposures in children born from 1993-2000
  - by category (infected, indeterminate, seroreverter)
  - with no known prenatal care, categorized by risk factor of mother
  - by percentage of children with any history of ZDV (076) protocol
- women reported between 1992 and 1999 who have a history of delivering a live-born infant(s) or who were currently pregnant at the time of report, by zip code and city of residence (data from the surveillance registry).

To conclude, it is important to overcome perceptions of how surveillance (number crunchers) appears to prevention and how prevention (the ones with all the money) appears to surveillance and focus on the prize of getting moms into prenatal care. Following a site visit, CDC recommended that our health department establish a way of examining all the perinatal HIV transmission failures that occur in the state. My recommendation is that we should do the same for the HIV-positive women found through outreach, i.e., look at them case-by-case and have your surveillance group track them and give the local perinatal workgroups *immediate feedback*. Of course, difficult issues remain surrounding case reporting, confidentiality, and measuring the impact of our programs.

Virginia Experience

Carol Burnham, HIV/STD Division, Virginia Department of Health

Virginia has three perinatal HIV prevention programs: a new Title IV program, a new program for prevention case management in northern Virginia, and a prevention case management program in the Richmond area. Although only one HIV-positive child was born in Virginia in the year 2000, we have identified lots of missed opportunities: HIV-positive women at delivery with no prenatal care, with no antiretroviral therapy and with no HIV prevention intervention at labor and delivery. This has led to the recognition of the need for prevention case management services.

Circle of Care–Philadelphia

Hal Shanis and Nina Gorman

The Circle of Care (Family Planning Council), Philadelphia, Pennsylvania

The Circle of Care is funded under Title IV to identify HIV-positive women and bring them in for care. It has two types of case management programs for maintaining these women in care: family services and perinatal case management.

The family services program provides case management for the whole family. Clients are followed via a coded I.D. Progress is tracked with data collection instruments. We have collected data on all services provided over the last 10 years.

The perinatal case management program is aimed at keeping pregnant women in prenatal care. Currently, about 40 HIV-positive women are enrolled at three OB/GYN sites. Data collection instruments include:

- intake forms (demographics, GYN and medical history, ZDV information, health care provider, etc.)
- encounter forms (social services referrals, HIV, CD4, and viral load tests, antiretroviral therapy, etc.)
- delivery forms (complications, type of delivery, etc.), and
- discharge forms (dissatisfaction with the program, medical issues, etc.)

We also track outcomes. We look at integration of the client into health care and case management systems (number of medical contacts with provider, number of referrals, time of first prenatal care, time of ZDV acceptance) and at the health of the infants (height, weight, head circumference, APGAR scores). Committee meetings are held to review all of the circumstances surrounding the birth of HIV-positive children.

Some of the research questions we are hoping to answer through this data collection include:

- Can class-based demographics predict outcomes?
- Can clusters of cognitive-based demographics predict outcomes?
- Can the extent of social support or economic support predict outcomes?
- Will the extent of HIV progression in the mother predict outcomes?
- Will pre-existing pregnancy conditions predict outcome?

Workshop 11: Collaboration Between Perinatal HIV Prevention and Maternal-Child Health Programs

Moderators: Sherry Orloff and Frances Varela

Health Resources and Services Administration

Doris Barnette, Office of the Administrator, HRSA

Under the current administrator of HRSA, there has been a real emphasis on collaboration across programs. Categorical grant programs are not going away; legislators relate to them and we will not see generic funding.

Therefore it is important to look for different funding sources and to realize that these new funds will not come without strings. Flexibility in how funding may be used may improve, but this flexibility will always come with accountability and, usually, more and more restrictions over time.

If grantees of different programs see collaboration as adding value to what they're doing, they will collaborate; otherwise, they will only pay lip-service to the idea.

Our job is to build capacity; federal agencies and federal grantees need to find other funding sources to enhance their efforts. This will mean collaborating with others, or the forming of partnerships where you can use their money and they will also benefit. We need to know the different funding sources out there and how to tap into them.

PRAMS, Title X Training, and Integration of Services

Mary Kay Larson, Division of Reproductive Health, Centers for Disease Control and Prevention

The Pregnancy Risk Assessment Monitoring System (PRAMS) is an ongoing, population-based surveillance system in which 24 states and the City of New York participate. The study population consists of women who recently delivered a live-born infant. Information is gathered on maternal behaviors and experiences around the time of pregnancy. HIV information has been collected since 1996, specifically whether health care providers discussed HIV prevention or testing during prenatal visits.

Based on PRAMS data from1998, 41%-55% of women recalled that their health care provider discussed HIV prevention during antenatal care and 70%-86% recalled that their health care provider discussed getting the blood test for HIV. The questionnaire was revised in 2000; mothers in all states who received any prenatal care are asked if their provider discussed HIV testing and several states will ask about actual testing.

PRAMS information and data are available on the Division of Reproductive Health's web site (http://www.cdc.gov/nccdphp/drh/). New grantees receiving funds for the PRAMS project will be announced on April 1.

Title X (family planning services) of the Public Health Services Act provides for training of health services providers, including training on HIV, through regional training centers. Through these regional centers, training has been provided to 4900 Title X- funded clinic health care providers serving close to 5 million women (85% from low-income households). Last year about 3000 service providers were trained on HIV (41% clinicians). A prenatal network through their Prenatal Smoking Cessation program already exists. This could be a way of "training the trainers" and of increasing voluntary counseling and testing in antenatal settings.

Integrating HIV services into family planning clinics or other settings may also be helped by through the use of patient flow analyses. These provide a documented snapshot of what's going on in the clinic (how personnel are being utilized and patients' movement through the clinic) and can be used to: a) measure performance of individual clinics; b) document the composition and use of clinic services; and c) document the effects of changes in procedures, time for each service, etc. This tool can thus be used to document the types of HIV counseling and testing women are receiving in antenatal clinics.

Perinatal HIV Prevention by Maternal and Child Health Programs

Frances Varela, Association of Maternal and Child Health Programs (AMCHP)

Title V of the Social Security Act of 1935 is the typical source of funding and guidance for maternal and child health (MCH) programs. MCH programs serve pregnant women, infants, and children. Health promotion activities under Title V include needs assessments of women, children (including children with special health care needs) and youth. Prevention of perinatal HIV can be a part of Title V programs; in fact, some states have specific MCH policies regarding prenatal HIV counseling and/or testing.

Last year AMCHP did a survey of MCH activities aimed at stopping the spread of perinatal HIV/AIDS. Thirteen states reported administering $25 million of AIDS money through MCH programs. Children with AIDS are eligible for MCH services under the children-with-special-needs provision.

The results of our survey indicated that there are numerous current activities in Title V programs to prevent the spread of HIV and AIDS, but there are still institutional obstacles to collaboration and allocation of resources (block grant funding).

Collaboration Efforts in Massachusetts

Deborah Allen, Massachusetts Department of Public Health

Traditionally there has been a division within Title V programs between services for women and services for children with special health care needs. Addressing the problem of perinatal HIV transmission challenges that division.

It's important to collaborate with Maternal and Child Health programs because that will give you access to relevant patients and providers. It will also provide data on the cascade that leads to transmission by identifying gaps in prevention services at different points in the cascade. Policy and health care providers' perception of who is at risk are good predictors of whether prevention services are delivered. A universal approach to the issue is important, but it's also important to know what is actually happening (particular approach).

Reaching out to varied state programs, for example, WIC, family planning, home visiting programs, and programs targeting children may address some of the gaps in perinatal HIV prevention that currently exist. However, these gaps may not be easily identified. Courtship is probably needed more than collaboration.

CityMatCH Project in Philadelphia

Rashidah Hassan, The Circle of Care (Family Planning Council)

A CDC-funded CityMatCH project is bringing cities together in "Learning Clusters" to share information on, among other urban-specific strategies to prevent perinatal HIV infection, how to integrate HIV and MCH services. Philadelphia was one of 5 cities in the original Learning Cluster, and the Circle of Care was one of the team members involved in the project.

The Circle of Care is a Title IV grantee that promotes "one-stop shopping" for mothers, children, fathers, etc. in Philadelphia's pediatric hospital centers. It is a project of the Family Planning Council and works with family planning services, private practitioners, and regional training centers to link services and

extend coverage for HIV-infected pregnant women. For example, in the regional training centers, it works with those who are learning how to do counseling and testing and trains them on how to deal with women's issues.

It's important to know what issues other programs face in delivering their services and to fit your needs into that environment. You also need to see what you can give to them. Although the Circle of Care has had much success in collaborating with other service providers, we are still trying to integrate mental health services and substance abuse treatment services with women's health issues. However, you need not go to the table thinking you need to give up something to ensure a collaboration. The CityMatCH project has been helpful in the development of strategies to facilitate linkages in care for HIV-infected pregnant women.

Discussion Summary

There was a question regarding how to get different state agencies to work together. One suggestion was to have outside groups with influence push state level officials to link services. Another approach to try was to have staff from different agencies work at the local level across services to find common areas of interest; and then push jointly to get action at the state government level for integrating and supporting efforts.

Sherry Orloff asked CityMatCH representatives from several cities to discuss their efforts to achieve improved services for HIV-infected pregnant women.

MCH in D.C. described their efforts working at several hospitals in D.C. and through outreach; and how they had been able to fund a social worker to help with outreach and other services.

Norfolk CityMatCH described a number of barriers to integrating MCH services within the health department and within WIC. They also indicated that bringing teenagers into antenatal care remained a big challenge.

All spoke of ideas shared across the CityMatCH programs.